

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

VANDA PHARMACEUTICALS INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA,
INC., et al.,

Defendants.

C.A. No. 18-651-CFC
(Consolidated)

**REDACTED –
PUBLIC VERSION**

JOINT [PROPOSED] PRETRIAL ORDER

This matter comes before the Court at a pretrial conference held pursuant to Rule 16 of the Federal Rules of Civil Procedure. Trial is scheduled to begin on March 28, 2022. In advance of the Pretrial Conference on March 9, 2022, counsel for Plaintiff Vanda Pharmaceuticals Inc. (“Plaintiff” or “Vanda”) and Defendants Teva Pharmaceuticals USA, Inc., Apotex Inc., and Apotex Corp. (collectively, “Defendants”) submit this Joint Proposed Pretrial Order governing trial of this action pursuant to Federal Rule of Civil Procedure 16, District of Delaware Local Rule 16.3, and the Scheduling Order, (D.I. 206, 238).¹

¹ Unless otherwise indicated, the docket numbers refer to C.A. No. 18-651.

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I. NATURE OF THE CASE AND PLEADINGS

1. This is a consolidated civil action for patent infringement, arising under the patent laws of the United States, Title 35, Section 101, *et seq.*, as well as the Hatch-Waxman Act, 21 U.S.C. § 355, against Defendants Teva Pharmaceutical USA, Inc. (“Teva”) and Apotex Inc. and Apotex Corp. (collectively, “Apotex”). This action was filed based on each Defendant’s filing of an Abbreviated New Drug Application (“ANDA”) with the Food and Drug Administration (“FDA”) seeking to market a generic version of Hetlio[®] (tasimelteon) capsules prior to the expiration of Vanda’s (1) U.S. Patent No. RE46,604 (“the RE604 patent”); (2) U.S. Patent No. 9,539,234 (“the ’234 patent”); (3) U.S. Patent No. 10,149,829 (“the ’829 patent”); (4) U.S. Patent No. 9,730,910 (“the ’910 patent”); (5) U.S. Patent No. 10,376,487 (“the ’487 patent”). This action was also filed based on Vanda’s contentions regarding each Defendant’s proposed manufacture or importation of tasimelteon for its ANDA product prior to the expiration of Vanda’s U.S. Patent No. 10,829,465 (“the ’465 patent”). Collectively, the above-referenced patents are referred to herein as the “Asserted Patents.”²

² To narrow the disputes for trial, and by agreement of the parties, Vanda is no longer asserting in this litigation claims from U.S. Patent Nos. 10,071,977 (the “’977 patent”); 10,610,510 (the “’510 patent”); 10,611,744 (the “’744 patent”); 10,449,176 (the “’176 patent”); 9,855,241 (the “’241 patent”); 9,060,995 (the “’995 patent”); 9,549,913 (the “’913 patent”); and 10,610,511 (the “’511 patent”).

2. Each of the civil actions referenced below has been consolidated under C.A. No. 18-651 (CFC) as the lead action.

A. Vanda

3. Vanda is a Delaware corporation with its principal place of business at 2200 Pennsylvania Avenue NW, Suite 300E, Washington, District of Columbia 20037.

4. Vanda is a pharmaceutical company that focuses on the development and commercialization of new medicines to address unmet medical needs, including Hetlioz[®] (tasimelteon oral capsules) for the treatment of Non-24-Hour Sleep-Wake Disorder (“Non-24”).

5. Vanda is the holder of approved New Drug Application No. 205677 for Hetlioz[®] capsules, 20 mg, which was approved by FDA on January 31, 2014, for the treatment of Non-24.

6. Vanda is the owner of all rights, title, and interest in the RE604, ’234, ’829, ’910, and ’487 patents. While Defendants dispute inventorship of the ’465 patent, Defendants do not otherwise contest that Vanda is the owner of all rights, title, and interest in the ’465 patent.

B. Teva

7. Teva is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

8. On April 30, 2018, Vanda sued Teva for alleged infringement of claims of the RE604, '995, '234, '913, '910, and '241 patents, (D.I. 1), based on Teva's submission of ANDA No. 211601 to FDA to obtain approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States generic tasimelteon capsules in its 20 mg strength for the treatment of Non-24 ("Teva's ANDA Product").

9. On June 21, 2018, Teva filed an answer, asserting affirmative defenses for non-infringement and invalidity, and counterclaims seeking a declaratory judgment that claims of the RE604, '995, '234, '913, '910, and '241 patents are invalid or would not be infringed, (D.I. 9).

10. On July 12, 2018, Vanda filed an answer denying the counterclaims, (D.I. 12).

11. On December 11, 2018, Vanda filed a first amended complaint against Teva, adding a count of infringement of claims of the '977 patent, (D.I. 41), based on Teva's submission of ANDA No. 211601 to FDA to obtain approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the

United States Teva's ANDA Product and Teva's "importing into the United States or offer[ing] to sell, sell[ing], or us[ing] within the United States a product which is made by a process patented in the United States" without authority, 35 U.S.C. § 271(g).

12. On December 21, 2018, Teva filed an answer to the amended complaint, asserting affirmative defenses of non-infringement and invalidity, and counterclaims seeking declaratory judgment that claims of the RE604, '995, '234, '913, '910, '241, and '977 patents are invalid, (D.I. 46).

13. On January 4, 2019, Vanda filed an answer denying the counterclaims, (D.I. 51).

14. On March 22, 2019, Vanda filed a complaint against Teva for infringement of the '829 patent, (C.A. No. 19-560, D.I. 1), based on Teva's submission of ANDA No. 211601 to FDA to obtain approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States Teva's ANDA Product.

15. On April 12, 2019, Teva filed an answer, asserting affirmative defenses for non-infringement and invalidity, and a counterclaim seeking declaratory judgment that claims of the '829 patent are invalid, (C.A. No. 19-560, D.I. 7).

16. On May 3, 2019, Vanda filed an answer denying the counterclaim, (C.A. No. 19-560, D.I. 10).

17. The two cases against Teva, (C.A. Nos. 18-651, 19-560), were consolidated on June 12, 2019 with C.A. No. 18-651 as the lead case, (D.I. 75; C.A. No. 19-560, D.I. 20).

18. On November 26, 2019, Vanda filed a complaint against Teva for infringement of claims of the '487 patent, (C.A. No. 19-2202, D.I. 1), based on Teva's submission of ANDA No. 211601 to FDA to obtain approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States Teva's ANDA Product.

19. On January 6, 2020, Teva filed an answer, asserting affirmative defenses for non-infringement and invalidity, and a counterclaim seeking declaratory judgment that claims of the '487 patent are invalid, (C.A. No. 19-2202, D.I. 9).

20. On January 22, 2020, Vanda filed a complaint against Teva for alleged infringement of claims of the '176 patent, (C.A. No. 20-93, D.I. 1), based on Teva's submission of ANDA No. 211601 to FDA to obtain approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States Teva's ANDA Product.

21. On January 27, 2020, Vanda filed an answer denying the counterclaim on the '487 patent, (C.A. No. 19-2202, D.I. 13).

22. On February 12, 2020, Teva filed an answer, asserting affirmative defenses for non-infringement and invalidity, and a counterclaim seeking a declaratory judgment that claims of the '176 patent are invalid, (C.A. No. 20-93, D.I. 9).

23. On March 2, 2020, Vanda filed an answer denying the counterclaim on the '176 patent, (C.A. No. 20-93, D.I. 13).

24. On May 5, 2020, the three cases against Teva, (C.A. Nos. 20-93, 19-2202, 18-651), were consolidated, with C.A. No. 18-651 as the lead case, (C.A. No. 20-93, D.I. 21 So Ordered; C.A. No. 19-2202, D.I. 25 So Ordered; D.I. 129 So Ordered).

25. On August 21, 2020, Vanda filed a complaint against Teva for infringement of claims of U.S. Patent No. 10,610,510 ("the '510 patent") and the '511 patent, (C.A. No. 20-1104, D.I. 1), based on Teva's submission of ANDA No. 211601 to FDA to obtain approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States Teva's ANDA Product.

26. On September 18, 2020, Teva filed an answer, asserting affirmative defenses for non-infringement and invalidity, and a counterclaim seeking declaratory judgment that claims of the '510 and '511 patents are invalid and non-infringed, (C.A. No. 20-1104, D.I. 8).

27. On October 9, 2020, Vanda filed an answer denying Teva's counterclaims, (C.A. No. 20-1104, D.I. 11).

28. On January 29, 2021, Vanda filed a complaint against Teva for infringement of claims of the '465 patent, (C.A. No. 21-121, D.I. 1), based on Teva's submission of ANDA No. 211601 to FDA to obtain approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States Teva's ANDA Product and Teva's "importing into the United States or offer[ing] to sell, sell[ing], or us[ing] within the United States a product which is made by a process patented in the United States" without authority, 35 U.S.C. § 271(g).

29. On February 3, 2021, the case against Teva on the '510 and '511 patents, (C.A. No. 20-1104), was consolidated with C.A. No. 18-651, (C.A. No. 20-1104, D.I. 23; D.I. 206).

30. On February 19, 2021, Teva filed an answer, asserting affirmative defenses for non-infringement and invalidity, and a counterclaim seeking declaratory judgment that claims of the '465 patent are invalid, (C.A. No. 21-121, D.I. 8).

31. On March 12, 2021, Vanda filed a first amended complaint against Teva, adding a count for infringement of claims of U.S. Patent No. 10,611,744 ("the '744 patent"), (C.A. No. 21-121, D.I. 11), based on Teva's submission of ANDA No. 211601 to FDA to obtain approval to commercially manufacture, use,

offer for sale, sell, distribute in, or import into the United States Teva's ANDA Product and Teva's "importing into the United States or offer[ing] to sell, sell[ing], or us[ing] within the United States a product which is made by a process patented in the United States" without authority, 35 U.S.C. § 271(g).

32. On March 12, 2021, Vanda filed an answer denying the counterclaim on the '465 patent, (C.A. No. 21-121, D.I. 13).

33. On March 26, 2021, Teva filed an answer, asserting affirmative defenses for non-infringement and invalidity, and counterclaims seeking declaratory judgment that claims of the '465 and '744 patents are invalid, (C.A. No. 21-121, D.I. 16).

34. On April 9, 2021, Vanda filed an answer denying Teva's counterclaims on the '465 and '744 patents, (C.A. No. 21-121, D.I. 17).

35. On April 26, 2021, the case against Teva on the '465 and '744 patents, (C.A. No. 21-121), was consolidated with C.A. No. 18-651, (C.A. No. 21-121, D.I. 22; D.I. 228).

C. Apotex

36. Apotex Inc. is a Canadian corporation with its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada. Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware with

its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. Apotex Corp. is a wholly owned subsidiary of Apotex Inc.

37. On May 7, 2018, Vanda sued Apotex for infringement of claims of the RE604 patent; the '995 patent; the '234 patent; the '913 patent; the '910 patent; and the '241 patent, (C.A. No. 18-689, D.I. 1), based on Apotex's submission of ANDA No. 211607 to FDA to obtain approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States generic tasimelteon capsules in its 20 mg strength for the treatment of Non-24 ("Apotex's ANDA Product").

38. On July 13, 2018, Apotex filed an answer, asserting affirmative defenses for non-infringement, invalidity, and failure to state a claim for exceptional case, (C.A. No. 18-689, D.I. 15).

39. On December 11, 2018, Vanda filed a first amended complaint against Apotex, adding a count for infringement of claims of the '977 patent, (C.A. No. 18-689, D.I. 46), based on Apotex's submission of ANDA No. 211607 to FDA to obtain approval to commercially manufacture and sell Apotex's ANDA Product and Apotex's "importing into the United States or offer[ing] to sell, sell[ing], or us[ing] within the United States a product which is made by a process patented in the United States" without authority, 35 U.S.C. § 271(g).

40. On December 26, 2018, Apotex filed an answer to the first amended complaint, asserting affirmative defenses for non-infringement, invalidity, and failure to state a claim for exceptional case, (C.A. No. 18-689, D.I. 53).

41. On April 12, 2019, Vanda filed an additional complaint against Apotex for infringement of claims of the '829 patent, (C.A. No. 19-685, D.I. 1), based on Apotex's submission of ANDA No. 211607 to FDA to obtain approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States Apotex's ANDA Product.

42. On May 7, 2019, Apotex filed an answer, asserting affirmative defenses for non-infringement, invalidity, and failure to state a claim for exceptional case, (C.A. No. 19-685, D.I. 9).

43. The two separate cases against Apotex, (C.A. Nos. 18-689 and 19-685), were consolidated on June 12, 2019 as C.A. No. 18-689 (C.A. No. 19-685, D.I. 21; C.A. No. 18-689, D.I. 79).

44. On December 30, 2019, Vanda filed an additional complaint against Apotex for infringement of claims of the '487 patent, (C.A. No. 19-2375, D.I. 1), based on Apotex's submission of ANDA No. 211607 to FDA to obtain approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States Apotex's ANDA Product.

45. On January 21, 2020, Apotex filed an answer, asserting affirmative defenses for non-infringement, invalidity, and failure to state a claim for exceptional case, (C.A. No. 19-2375, D.I. 13).

46. On January 21, 2020, Vanda filed an additional complaint against Apotex for infringement of the '176 patent, (C.A. No. 20-83, D.I. 1), based on Apotex's submission of ANDA No. 211607 to FDA to obtain approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States Apotex's ANDA Product.

47. On February 12, 2020, Apotex filed an answer, asserting affirmative defenses for non-infringement, invalidity, and failure to state a claim for exceptional case, (C.A. No. 20-83, D.I. 10).

48. On May 5, 2020, Vanda's three existing cases against Apotex, (C.A. Nos. 18-689, 19-2375, and 20-83), were consolidated with C.A. No. 18-651, (C.A. No. 18-689, D.I. 132 So Ordered; C.A. No. 19-2375, D.I. 23 So Ordered; C.A. No. 20-83, D.I. 20 So Ordered).

49. On October 1, 2020, Vanda filed an additional complaint against Apotex for infringement of claims of the '510 and '511 patents, (C.A. No. 20-1333, D.I. 1), based on Apotex's submission of ANDA No. 211607 to FDA to obtain approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States Apotex's ANDA Product.

50. On October 28, 2020, Apotex filed an answer, asserting affirmative defenses for non-infringement, invalidity, and failure to state a claim for exceptional case, (C.A. No. 20-1333, D.I. 10).

51. On February 3, 2021, the case against Apotex on the '510 and '511 patents, (C.A. No. 20-1333), was consolidated with C.A. No. 18-651, (C.A. No. 20-1333, D.I. 23; D.I. 203).

52. On February 24, 2021, Vanda filed an additional complaint against Apotex for infringement of claims of the '465 patent, (C.A. No. 21-282, D.I. 1), based on Apotex's submission of ANDA No. 211607 to FDA to obtain approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States Apotex's ANDA Product and Apotex's "importing into the United States or offer[ing] to sell, sell[ing], or us[ing] within the United States a product which is made by a process patented in the United States" without authority, 35 U.S.C. § 271(g).

53. On March 12, 2021, Vanda filed a first amended complaint against Apotex, adding a count of infringement of claims of the '744 patent, (C.A. No. 21-282, D.I. 10), based on Apotex's submission of ANDA No. 211607 to FDA to obtain approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States Apotex's ANDA Product and Apotex's "importing into the United States or offer[ing] to sell, sell[ing], or us[ing] within the United States a

product which is made by a process patented in the United States” without authority, 35 U.S.C. § 271(g).

54. On April 26, 2021, the case against Apotex on the '465 and '744 patents, (C.A. No. 21-282), was consolidated with C.A. No. 18-651, (C.A. No. 21-282, D.I. 21; D.I. 228).

II. JURISDICTION AND STANDING

55. This action arises under the patent laws of the United States, Title 35, United States Code. This Court has jurisdiction over the subject matter of this litigation action pursuant to 35 U.S.C. §§ 271, *et seq.*, and 28 U.S.C. §§ 1331 and 1338.

56. For the purposes of this action, no party contests personal jurisdiction in this Court.

57. For the purposes of this action, no party contests venue in this Court.

58. For the purposes of this action, Vanda asserts that it has standing as the record owner of the Asserted Patents, and Defendants do not dispute Vanda's standing. Defendants agree that Vanda need not present proof of this at trial.

III. STIPULATED FACTS

59. The parties stipulate to and admit the facts listed in the Joint Statement of Uncontested Facts attached as **Exhibit 1**. These stipulated facts require no proof at trial and will become part of the evidentiary record in this case.

IV. DISPUTED FACTS

60. Vanda's Statement of Contested Issues of Fact that remain to be litigated is attached as **Exhibit 2**.

61. Defendants' Statement of Contested Issues of Fact that remain to be litigated is attached as **Exhibit 3**.

62. If any statement in a party's statement of contested issues of fact should properly be considered an issue of law, then such statement shall be so considered as an issue of law.

V. ISSUES OF LAW

63. Vanda's Statement of Contested Issues of Law that remain to be litigated is attached as **Exhibit 4**.

64. Defendants' Statement of Contested Issues of Law that remain to be litigated is attached as **Exhibit 5**.

65. If any statement in a party's statement of contested issues of law that remain to be litigated should properly be considered an issue of fact, then such statement shall be so considered as an issue of fact.

VI. EXHIBITS

A. Trial Exhibits

66. The list of pre-marked trial exhibits that may be offered by Vanda is attached as **Exhibit 10**. Vanda's trial exhibits will be identified with PTX numbers.

67. The list of pre-marked trial exhibits that may be offered by Defendants is attached as **Exhibit 11**. Defendants' trial exhibit lists will be identified with DTX numbers.

68. The joint list of pre-marked trial exhibits that may be offered by any party is attached as **Exhibit 12**. The parties' joint trial exhibits will be identified by JTX numbers.

69. Vanda and Defendants each reserve the right to offer exhibits set forth on the others' exhibit list, even if not set forth on their own exhibit list, and each party reserves the right to raise objections to the use of the exhibit by the offering party, including if the exhibit is on the opposing party's exhibit list. All objections to such exhibits are preserved. The parties shall not remove a document once it has been added to the party's exhibit list without agreement from the other party, unless it provides the other party the opportunity to add the document to its exhibit list.

70. This pretrial order contains the parties' good faith efforts to identify the universe of exhibits to be used in any party's case. By submitting the exhibit lists attached to this pretrial order, each party represents that it presently knows of no additional exhibits it intends to add to its list. To the extent supplemental exhibits are identified, the parties agree to disclose any supplemental exhibits promptly after identification, and each party reserves the right to object to such supplemental exhibits as untimely, as well as on the other bases (e.g., hearsay, relevance) to which

exhibits may generally be objected. Absent agreement of the parties or good cause shown, no party may add an exhibit to its exhibit list after the Pretrial Conference. Notwithstanding the foregoing, the parties reserve the right to offer additional exhibits for impeachment purposes.

71. The parties reserve their rights to raise all objections to exhibits as set forth on the trial exhibit lists, subject to the parties' stipulations, and pursuant to the procedures set forth at paragraphs 78–80.

72. The listing of an exhibit on a party's trial exhibit list does not constitute an admission as to the relevance or admissibility of that trial exhibit. Each party reserves the right to object to the relevance or admissibility of any evidence offered by another party at the time such evidence is offered and in view of the specific context in which such evidence is offered. The parties agree that any description of a document on an exhibit list is provided for convenience only and shall not be used as an admission or otherwise as evidence regarding the document. Nothing herein shall be construed as a stipulation or admission that a document is entitled to any weight in deciding the merits of this case.

73. On or before the first day of trial, counsel will deliver to the Courtroom Deputy a completed AO Form 187 exhibit list for each party.

1. Stipulations Concerning Trial Exhibits

74. Absent agreement of the parties or order of the Court, no exhibit will be admitted unless offered into evidence through a witness, including through deposition, who must at least be shown the exhibit.

75. Any exhibit, once admitted, may be used equally by each party for any proper purpose in accordance with the Federal Rules of Evidence.

76. Any trial exhibit that was produced in discovery by a party and that on its face appears to have been authored by an employee, officer, or agent of the party that produced such document, will be deemed to be a true and correct copy of a document maintained in that producing party's files as of the date of the party's document collection under Federal Rule of Evidence 901. No foundation need be laid for the authenticity of such documents at trial. For clarity, this provision does not obviate the need to otherwise lay the proper foundation for admissibility of a document or of testimony about that document (e.g., relevance or personal knowledge of a fact witness). This provision also does not obviate the need to establish the date of any document and does not obviate Defendants' burden to establish that any asserted document or reference qualifies as prior art under 35 U.S.C. § 102. The parties reserve the right to object to the introduction into evidence of the documents and files referenced in this provision (in whole or in part) on all other grounds.

77. No party shall object on the grounds of authenticity to the introduction into evidence of any document through deposition designation testimony of a fact witness that references that document. Legible copies of documents may be offered and received into evidence to the same extent as an original. The parties may substitute pre-marked exhibits identified on Exhibits 10 and 11 with color copies and/or more legible versions provided that the content and text is identical to that which was previously identified in Exhibits 10 and 11 and previously exchanged among the parties in preparing this Joint [Proposed] Pretrial Order. For particularly voluminous documents (e.g., patent application file histories, New Drug Applications, Abbreviated New Drug Applications, and Drug Master Files), the parties may use excerpts of documents identified on their exhibit lists, provided: (i) such excerpts do not mischaracterize or misrepresent the contents of the document as a whole; (ii) such excerpts are disclosed in accordance with the procedures set forth below, in Section VI.A.2; and (iii) the other party is permitted to add a reasonable number of pages to the intended excerpt necessary to provide adequate context and completeness for the intended excerpt.

2. Procedure for Trial Exhibit Disclosure

78. Each party shall provide by email to opposing counsel a list of all exhibits (by exhibit number) that party intends to use in direct examination of witnesses by 7:00 p.m. two calendar days before they will be used at trial. For

example, a listing of all exhibits intended for use during direct examination of witnesses on Monday, March 28, 2022, would be exchanged by email before 7:00 p.m. on Saturday, March 26, 2022. A party seeking to substitute a pre-marked exhibit with a color and/or more legible version of the same, pursuant to paragraph 77, shall provide such substitutions at this time. Notwithstanding the foregoing, each party reserves the right to amend or supplement the list with a reasonable number of exhibits provided such exhibits are promptly identified.

79. The party receiving identification of exhibits intended for use in direct examination of witnesses pursuant to the previous paragraph shall inform the party identifying the exhibits of any objections by 8:30 p.m. on the day after receipt, and the parties shall meet and confer as soon as possible thereafter, but by no later than 9:30 p.m. on the day after receipt to resolve such objections. Any unresolved objections shall be brought to the Court's attention for resolution no later than the start of the trial day on which the exhibit is intended to be used.

80. Prior to the start of direct examination of a particular witness, the party conducting the direct examination will provide the other party with two copies of binders containing all exhibits and demonstrative exhibits that they intend to use with that witness on direct examination and will provide all required copies to the Court. The parties agree that this provision does not require the advanced disclosure of exhibits to be used to impeach or on cross-examination of any witness, provided

such exhibits were identified on a party's exhibit list (i.e., Exhibits 10–12) unless used solely for purposes of impeachment. However, prior to the start of the cross-examination of any witness, the parties agree to provide the other with two copies of witness binders that contain all of the exhibits expected to be used on cross-examination of that witness and will provide all required copies to the Court.

B. Demonstrative Exhibits

81. The parties may use demonstrative exhibits, which do not need to be identified on their respective lists of trial exhibits. Vanda's demonstrative exhibits will be identified with PDX numbers. Defendants' demonstrative exhibits will be identified with DDX numbers.

82. Each demonstrative exhibit shall identify by exhibit number all trial exhibits that form the basis of the demonstrative exhibit. Such identified trial exhibits referenced in the demonstrative exhibit and shown to a witness shall be offered into evidence during or at the conclusion of the examination for the witness with whom the demonstratives were used.

83. Each party will exchange copies of demonstrative trial exhibits expected to be used during the direct examination of a witness by e-mail by 7:00 p.m. on the calendar day before their intended use, with an agreement that any changes to the demonstratives made after such exchange will be only edits to font, layout, format, or to correct typographical errors and not edits of substance, unless made in

response to and for the purpose of resolving an objection. Any objections will be provided no later than 8:30 p.m. on the calendar day before their intended use, and the parties shall meet and confer as soon as possible thereafter but by no later than 9:30 p.m. to resolve such objections. If the parties' meet and confer session causes the party offering the demonstrative exhibit to make edits of substance, that party shall disclose the revised exhibit to the objecting party as soon as possible. Any unresolved objections shall be brought to the Court's attention for resolution no later than the start of the trial day on which the demonstrative exhibit is intended to be used. For example, demonstrative trial exhibits intended for use during the direct examination of a witness at trial on Monday, March 28, 2022, would be exchanged by email before 7:00 p.m. on Sunday, March 27, 2022; any objections would be exchanged by email before 8:30 p.m. on Sunday; the parties would meet and confer about any objections before 9:30 p.m. on Sunday; and any unresolved objections would be brought to the Court's attention for resolution by Monday morning before the start of the trial day.

84. The party seeking to use a demonstrative will provide a color representation of the demonstrative to the other side in PDF form. For video or animations, the party seeking to use the demonstrative will provide it to the other side in an appropriate electronic format to view the video or animation. For

irregularly sized physical exhibits, the party seeking to use the demonstrative will provide a color representation as a PDF of 8.5 x 11 copies of the exhibits.

85. The parties need not exchange in advance of their use any demonstrative exhibits that are created during testimony or demonstratives that are used solely on cross-examination with a witness.

86. **Openings.** Trial exhibits and demonstrative exhibits to be used with opening statements shall be exchanged via email by 7:00 p.m. on the calendar day before the day opening statements are to be given. The materials to be exchanged for opening statements will be the same as for all other exchanges for trial and demonstrative exhibits. For example, trial and demonstrative exhibits intended for use with opening statements would be exchanged by email before 7:00 p.m. on Sunday, March 27, 2022. Any objections shall be exchanged by 8:30 p.m. on the day of receipt, and the parties shall meet and confer as soon as possible thereafter but by no later than 9:30 p.m. to resolve such objections. The parties agree that any changes to these materials made after 7:00 p.m. on the evening before opening statements are made will be non-substantive (e.g., edits to font, layout, format, or to correct typographical errors) unless made in response to and for the purpose of resolving an objection. Any unresolved objections shall be brought to the Court's attention at the start of the trial day before opening statements are made.

87. **Closings.** The parties need not exchange demonstratives for use in closing arguments.

VII. WITNESSES

88. Vanda's list of witnesses it may call live at trial and by deposition, together with Defendants' objections, is attached as **Exhibit 6**, and **Exhibit 17** provides additional information on Vanda's experts' specialties and qualifications.

89. For witnesses that will appear by deposition, Vanda's list of deposition designations, Defendants' objections to such designations, Defendants' counter-designations, and Vanda's objections to such counter-designations is attached as **Exhibit 8**.

90. Defendants' list of witnesses they may call live at trial and by deposition, together with Vanda's objections, is attached as **Exhibit 7**, and **Exhibit 18** provides additional information on Defendants' experts' specific specialties and qualifications.

91. For witnesses that will appear by deposition, Defendants' list of deposition designations, Vanda's objections to such designations, Vanda's counter-designations, and Defendants' objections to such counter-designations is attached as **Exhibit 9**.

92. The listing of a witness on a party's witness list does not require the party to call that witness to testify, and does not imply or establish that the listing

party has the power to compel the live testimony of that witness or make that witness available to the opposing party.

93. Any witness not listed in Exhibits 6 and 7 will be precluded from testifying at trial absent good cause shown. The parties reserve the right, however, to call one or more additional witnesses whose testimony is necessary to establish admissibility of any trial exhibit, if the admissibility of the exhibit is challenged by an opposing party.

94. Exhibits 8 and 9 contain the maximum universe of deposition designations, counter-designations, and objections to admission of deposition testimony; none of the foregoing may be supplemented without approval of both parties or leave of the Court, on good cause shown, although parties may object to deposition designations based on future Court rulings on pending motions *in limine*. Each party reserves the right to object to the relevance or admissibility of any evidence offered by another party at the time such evidence is offered and in view of the specific context in which such evidence is offered. These designations cover witnesses who will testify via deposition. The parties are not required to designate deposition testimony that will be used for impeachment or deposition testimony that an expert will rely on during their trial testimony so long as that deposition testimony was cited in that expert's report. In the event that a party cannot or does not call any designated "will call" live witness to trial, the other party may identify additional

designations to which the other party may object and offer counter designations. All objections and colloquy of counsel will be eliminated from the deposition designations when the designations are read or played to the Court.

95. The parties may not introduce deposition designations or counter-designations, or provide new objections to listed designations or counter-designations that are not included in this Proposed Joint Pretrial Order except for good cause shown or by agreement of the parties.

96. The parties' witness lists represent the parties' good faith understanding and expectation about which witnesses are expected to be called live in person, or by deposition, at trial. To the extent that a witness's circumstances change, or a witness otherwise becomes unavailable for trial, each party reserves the right to call that witness by deposition to the extent permitted under the Federal Rules of Civil Procedure and the Federal Rules of Evidence and subject to resolution of objections by the other party.

97. Each party will provide to the other a good-faith list of witnesses it intends to call live at the trial via email by 7:00 p.m. seven calendar days prior to the first day of trial, without prejudice to the right to remove any witness. Each party will, with its best good faith understanding, identify by e-mail to the opposing party the witnesses it intends to call, the order in which the witnesses will be called, and whether those witnesses will be called live or by deposition, by 7:00 p.m. two

calendar days before such witnesses will be called to testify. The parties reserve the right to revise, in good faith, their witness identifications, including order, following the close of the other party's case-in-chief or rebuttal case.

98. The other party will identify any objections to such witnesses via email by 8:30 p.m. the same day, and the parties will meet and confer to resolve any objections by 9:30 p.m. that same evening. If good faith efforts to resolve any objections fail, the party objecting may bring its objections to the Court's attention prior to the witness being called to the witness stand.

99. Fact witnesses appearing in person (other than a party's corporate representative) shall be sequestered. Expert witnesses need not be sequestered.

100. During adjournments in the trial of no more than five days, including breaks during the trial day and overnight, the offering party may discuss with a witness his or her testimony on direct examination until the witness is passed for cross-examination and cross-examination has commenced, but is prohibited from discussing with the witness his or her testimony once cross-examination has begun. Once cross-examination of the witness is concluded and the witness is passed for re-direct examination, the offering party may discuss with the witness his or her testimony on re-direct examination.

101. Unless otherwise agreed between the parties, the party offering deposition testimony shall identify the deposition testimony (i.e., transcript page and

line numbers) to be offered from previously exchanged designations by 7:00 p.m. three calendar days prior to the testimony being offered into the record. The party receiving the designations shall inform the opposing party of any objections and counter-designations by 7:00 p.m. two calendar days prior to the testimony being offered into the record, and by 8:30 p.m. that same day, the introducing party will identify any objections to the other party's counter-designated testimony. The parties shall meet and confer to resolve any objections to designated testimony by 9:30 p.m. that same day to permit sufficient time to prepare any necessary video/DVD of the testimony. If good faith efforts to resolve the objections fail, the party offering the testimony by deposition shall, on the morning of the day on which the witness is to be called at trial, submit to the Court, on behalf of all parties, a copy of the entire deposition testimony of the witness at issue, clearly highlighting the designations, counter designations, and pending objections.

102. If a party decides to play some but less than all of the designated testimony for a witness at trial, the opposing party may use such dropped testimony as counter-designations to the extent the usage of such testimony in such manner is otherwise consistent with Federal Rule of Evidence 106, Federal Rule of Civil Procedure 32, and any other applicable Federal Rule of Evidence or Rule of Civil Procedure.

103. If applicable, a party's designation of a page and line from a particular transcript shall be automatically deemed to include any errata indicated for that page and line in the attached errata sheets.

104. To the extent that deposition designations or counter-designations are admitted into evidence, they must be either played by video or read in open court. If a party opts to introduce deposition testimony, any counter-designation of that same witness's testimony must be admitted in the same medium, and the testimony designated by both sides will be played or read consecutively in the sequence in which the testimony was originally given at deposition. If an exhibit is referenced in a deposition designation, the exhibit is admitted into evidence if it is included on any party's trial exhibit list and is not otherwise objected to, subject to Section VI.

105. To the extent deposition designations are read or played in open court, each side will be charged the time taken to read or play its designations (or counter-designations). Specifically, any affirmative designations offered by a party will count against that party's trial presentation time whereas any counter-designations by the other party will count against the party who made the counter-designations. The time charged for designations played by video will be measured by the time on the video. The time charged for designations read aloud will be measured by the proportion of the number of lines of testimony for its designations to the total number of lines of testimony read. All irrelevant and redundant material, including colloquy

between counsel and objections, will be eliminated when the deposition is played or read at trial.

106. The above procedures regarding deposition designations do not apply to portions of deposition transcripts and/or video of a witness used for impeachment. Any deposition testimony of a witness may be used at trial for the purpose of impeachment of that witness, regardless of whether a party specifically identified that testimony on its list of deposition designations, if the testimony is otherwise competent for such purpose.

107. **Objections to expert testimony.** The parties agree that the Court should rule at trial on any objections to expert testimony as beyond the scope of prior expert disclosures, and that a failure to object to expert testimony as beyond the scope of prior expert disclosures waives the objection as to that testimony. The time taken to argue and decide such objections will be taken from the time for trial available to either the party making the objection, if the objection is overruled, or the party against whom the objection is made, if the objection is sustained.

VIII. BRIEF STATEMENT OF INTENDED PROOFS

108. In support of its claims and defenses relating to the infringement and validity of the Asserted Patents, and in addition to the facts not in dispute, Vanda expects to offer the proofs attached as **Exhibit 13**.

109. In support of their claims and defenses relating to the non-infringement and invalidity of the Asserted Patents, and in addition to the facts not in dispute, Defendants expect to offer the proofs attached as **Exhibit 14**.

IX. DESIRED AMENDMENTS TO THE PLEADINGS

110. The parties do not believe any amendments to the pleadings are necessary.

X. CERTIFICATION OF SETTLEMENT DISCUSSIONS

111. The parties have engaged in good-faith efforts to explore resolution of this case by settlement. To date, no agreement has been reached by the parties.

XI. MOTIONS *IN LIMINE*

112. None filed.

XII. MISCELLANEOUS ISSUES

A. Damages

113. Vanda does not seek damages at this time, as there has been no commercial launch of Defendants' ANDA products, except Vanda reserves the right to seek attorneys' fees, costs, and expenses pursuant to 35 U.S.C. § 285. Vanda reserves the right to seek damages if any Defendant commercially manufactures, uses, sells, offers to sell, or imports into the United States its accused ANDA Products prior to the expiration of the Asserted Patents. Defendants reserve the right to contest whether Vanda is entitled to attorneys' fees, costs, and expenses or any such damages. Teva reserves the right to seek attorneys' fees and costs pursuant to

35 U.S.C. § 285. Apotex reserves the right to seek attorneys' fees and costs pursuant to 35 U.S.C. § 285.

B. Expert Testimony

114. Expert witnesses may not offer previously undisclosed opinions.

C. Trial Parameters

115. This case is currently scheduled for a five-day bench trial beginning at 8:30 a.m. on **March 28, 2022**, with the subsequent trial days at 8:30 a.m. The trial will be timed, as counsel will be allocated a total number of hours in which to present their respective cases. The parties request that the total time be split equally between Vanda, on the one hand, and the Defendants collectively, on the other. The parties would seek to discuss with the Court at the pretrial conference the Court's intended daily schedule, to arrive at an aggregate expected amount of trial time, which they will then divide equally.

116. This is a non-jury trial.

117. Subject to the Court's standard timekeeping procedures, time that a party is presenting opening statements, examining or cross-examining witnesses, presenting deposition designations that are read or played into evidence, or otherwise speaking or arguing on behalf of a party will be counted as the time of the party, subject to paragraph 136. The parties also respectfully request the opportunity to

present closing arguments. The Court will maintain the official total of trial time used by each side.

118. The following order of proof will apply to trial:

- a. Opening statements will be delivered in the following order:
Vanda, then Defendants;
- b. Vanda will present its case-in-chief on infringement and fact witness testimony (i.e., testimony of witnesses who did not submit expert reports pursuant to Fed. R. Civ. 26) on secondary considerations;
- c. Defendants will present their rebuttal to infringement, their case-in-chief on invalidity, and their fact witness rebuttal to Vanda's fact witness testimony on secondary considerations;
- d. Vanda will present its rebuttal to invalidity, including its expert testimony regarding secondary considerations;
- e. Defendants will present their rebuttal to Vanda's expert witness testimony regarding secondary considerations;
- f. Closings will be delivered in the following order: Vanda, then Defendants, with a reply by Vanda.

D. Additional Matters

119. **Pretrial Conference.** Pursuant to D.I. 206, C.A. No. 18-651, the Pretrial Conference will be held on March 9, 2022 at 2:00 p.m.

120. **COVID Protocols.**

1. **Vaccinations.** The parties agree that any individual under their respective control (including, but not limited to, attorneys, paralegals, in-house counsel, witnesses, and vendors) shall be fully vaccinated³ in order to enter the courtroom.

2. **Masking.** Subject to the Court's preferences, the parties agree that all individuals under their respective control (including, but not limited to, attorneys, paralegals, in-house counsel, witnesses and vendors) shall be masked in the courtroom, except that anyone directly addressing the Court shall remove their mask while they address the Court.

3. **Distancing.** The parties shall endeavor to maintain social distancing to the extent possible, including, at counsel's election and if permitted by the Court, by examining witnesses from counsel table. An individual who is moving in the courtroom shall wear a mask while moving.

³ "Fully vaccinated" shall mean two weeks past the final dose.

Dated: February 16, 2022

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SO ORDERED this _____ day of _____, 2022.

Chief United States District Judge

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

VANDA PHARMACEUTICALS
INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA,
INC., et al.,

Defendants.

C.A. No. 18-651-CFC
(Consolidated)

Exhibit 1 – Joint Statement of Uncontested Facts

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I. INTRODUCTION

In accordance with Local Rule 16.3(c)(3) of the Local Rules of Civil Practice and Procedure of the United States District Court for the District of Delaware, Plaintiff Vanda Pharmaceuticals, Inc. (“Vanda”) and Defendants (i) Teva Pharmaceuticals USA, Inc. (“Teva”); and (ii) Apotex Inc. and Apotex Corp. (collectively, “Apotex” with Teva, “Defendants”) submit the following joint statement of the facts that are admitted and require no proof, with respect to the following asserted patents:

- (i) U.S. Patent No. RE46,604 (“the RE604 patent”);
- (ii) U.S. Patent No. 9,539,234 (“the ’234 patent”);
- (iii) U.S. Patent No. 10,149,829 (“the ’829 patent”);
- (iv) U.S. Patent No. 9,730,910 (“the ’910 patent”);
- (v) U.S. Patent No. 10,376,487 (“the ’487 patent”); and
- (vi) (xi) U.S. Patent No. 10,829,465 (“the ’465 patent”) (collectively, the “Asserted Patents”).

The asserted claims of the Asserted Patents (“Asserted Claims”) are¹:

U.S. Patent No.	Asserted Claims
RE46,604 (the RE604 patent)	3
9,539,234 (the ’234 patent)	4
10,149,829 (the ’829 patent)	14
9,730,910 (the ’910 patent)	4
10,376,487 (the ’487 patent)	5
10,829,465 (the ’465 patent)	10

II. BACKGROUND FACTS

A. The Parties

1. Vanda is a Delaware corporation with its principal place of business at 2200 Pennsylvania Avenue NW, Suite 300E, Washington, District of Columbia 20037.

2. Vanda is the owner of record of all rights, title, and interest in each of the Asserted Patents.

3. Teva is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 400 Interpace Parkway,

¹ To narrow the disputes for trial, and by agreement of the parties, Vanda is no longer asserting in this litigation claims from U.S. Patent Nos. 10,071,977 (the “’977 patent”); 10,610,510 (the “’510 patent”); 10,611,744 (the “’744 patent”); 10,449,176 (the “’176 patent”); 9,855,241 (the “’241 patent”); 9,060,995 (the “’995 patent”); 9,549,913 (the “’913 patent”); and 10,610,511 (the “’511 patent”).

Parsippany, New Jersey 07054. For purposes of this matter only, Teva does not contest personal jurisdiction, subject matter jurisdiction, or venue in this Court.

4. Apotex Inc. is a Canadian corporation with its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada. Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. For purposes of this matter only, Apotex Inc. and Apotex Corp. do not contest personal jurisdiction, subject matter jurisdiction, or venue in this Court.

B. Plaintiff's HETLIOZ[®] Product

6. Vanda is the holder of approved New Drug Application No. 205677 for HETLIOZ[®] (tasimelteon) 20 mg capsules.

7. HETLIOZ[®] (tasimelteon) 20 mg capsules received Food and Drug Administration ("FDA") approval on January 31, 2014 for the treatment of Non-24 Hour Sleep-Wake Disorder ("Non-24").

8. Vanda markets 20 mg tasimelteon capsules in the United States under the trade name HETLIOZ[®].

9. All the Asserted Patents are listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") for HETLIOZ[®] (tasimelteon) 20 mg capsules.

C. Defendants' Tasimelteon Products

1. Teva's ANDA Product

12. Teva filed ANDA No. 211601 ("Teva's ANDA") under § 505(j) of the Federal Food, Drug, and Cosmetic Act (the "FFDCA") to obtain approval to engage in the commercial use, manufacture, and sale of generic 20 mg tasimelteon capsules ("Teva's ANDA Product") for the treatment of Non-24.

13. [REDACTED].

14. Teva's ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(a)(vii)(IV) (a "Paragraph IV Certification") alleging that each of the Asserted Claims is invalid and/or unenforceable and/or will not be infringed by Teva's ANDA Product.

15. Vanda received written notice of Teva's ANDA and Paragraph IV Certification on March 23, 2018, along with an enclosed statement of Teva's asserted factual and legal bases for stating that the claims of the RE604, '995, '234, '913, '910, and '241 patents, including claim 3 of the RE604 patent, claim 4 of the '234 patent, and claim 4 of the '910 patent, are invalid and/or will not be infringed by Teva's ANDA Product. Vanda sued Teva for infringing claims of the RE604, '995, '234, '913, '910, and '241 patents on April 30, 2018, within the 45-day period following receipt of the written notice under 21 U.S.C. §355(j)(5)(B)(iii).

16. Vanda received written notice of Teva's ANDA and Paragraph IV Certification as to the '829 patent on February 7, 2019, along with an enclosed statement of Teva's asserted factual and legal bases for stating that the claims of the '829 patent, including claim 14, are invalid and/or will not be infringed by Teva's ANDA Product. Vanda sued Teva for infringing claims of the '829 patent on March 22, 2019, within the 45-day period following receipt of the written notice under 21 U.S.C. §355(j)(5)(B)(iii).

17. Vanda received written notice of Teva's ANDA and Paragraph IV Certification as to the '487 patent on October 16, 2019, along with an enclosed statement of Teva's asserted factual and legal bases for stating that the claims of the '487 patent, including claim 5, are invalid and/or will not be infringed by Teva's ANDA Product. Vanda sued Teva for infringing claims of the '487 patent on November 26, 2019, within the 45-day period following receipt of the written notice under 21 U.S.C. §355(j)(5)(B)(iii).

18. Vanda received written notice of Teva's ANDA and Paragraph IV Certification as to the '176 patent on December 20, 2019, along with an enclosed statement of Teva's asserted factual and legal bases for stating that the claims of the '176 patent are invalid and/or will not be infringed by Teva's ANDA Product. Vanda sued Teva for infringing claims of the '176 patent on January 22, 2020, within

the 45-day period following receipt of the written notice under 21 U.S.C. §355(j)(5)(B)(iii).

19. Vanda received written notice of Teva's ANDA and Paragraph IV Certification as to the '511 patent on July 10, 2020, along with an enclosed statement of Teva's asserted factual and legal bases for stating that the claims of the '511 patent are invalid and/or will not be infringed by Teva's ANDA Product. Vanda sued Teva for infringing claims of the '511 patent on August 21, 2020, within the 45-day period following receipt of the written notice under 21 U.S.C. §355(j)(5)(B)(iii).

20. Vanda received written notice of Teva's ANDA and Paragraph IV Certification as to the '465 patent on December 18, 2020, along with an enclosed statement of Teva's asserted factual and legal bases for stating that the claims of the '465 patent, including claim 10, are invalid and/or will not be infringed by Teva's ANDA Product. Vanda sued Teva for infringing claims of the '465 patent on January 29, 2021, within the 45-day period following receipt of the written notice under 21 U.S.C. §355(j)(5)(B)(iii).

2. Apotex's ANDA Product

21. Apotex filed ANDA No. 211607 ("Apotex's ANDA") under § 505(j) of the Federal Food, Drug, and Cosmetic Act, to obtain approval to engage in the

commercial use, manufacture, and sale of generic 20 mg tasimelteon capsules (“Apotex’s ANDA Product”) for the treatment of Non-24.

22. [REDACTED]

[REDACTED]

23. Apotex’s ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(a)(vii)(IV) (“a Paragraph IV Certification”) alleging that each of the Asserted Claims, is invalid and/or, except for claim 5 of the ’487 patent and claim 10 of the ’465 patent, will not be infringed by Apotex’s ANDA Product.

24. Vanda received written notice of Apotex’s ANDA and Paragraph IV Certification on April 3, 2018, along with an enclosed statement of Apotex’s asserted factual and legal bases for stating that the claims of the RE604, ’995, ’234, ’913, ’910, and ’241 patents, including claim 3 of the RE604 patent, claim 4 of the ’234 patent, and claim 4 of the ’910 patent, are invalid and/or will not be infringed by Apotex’s ANDA Product. Vanda sued Apotex for infringing claims of the RE604, ’995, ’234, ’913, ’910, and ’241 patents on May 7, 2018, within the 45-day period following receipt of the written notice under 21 U.S.C. §355(j)(5)(B)(iii).

25. Vanda received written notice of Apotex’s ANDA and Paragraph IV Certification as to the ’829 patent on February 28, 2019, along with an enclosed statement of Apotex’s asserted factual and legal bases for stating that the claims of the ’829 patent, including claim 14, are invalid and/or will not be infringed by

Apotex's ANDA Product. Vanda sued Apotex for infringing claims of the '829 patent on April 12, 2019, within the 45-day period following receipt of the written notice under 21 U.S.C. §355(j)(5)(B)(iii).

26. Vanda received written notice of Apotex's ANDA and Paragraph IV Certification as to the '487 patent on November 22, 2019, along with an enclosed statement of Apotex's asserted factual and legal bases for stating that the claims of the '487 patent, including claim 5, are invalid and/or that certain unasserted claims of the '487 patent will not be infringed by Apotex's ANDA Product. The Paragraph IV Certification did not provide any factual or legal bases for stating that claim 5 of the '487 patent will not be infringed by Apotex's ANDA Product. Vanda sued Apotex for infringing claims of the '487 patent on December 30, 2019, within the 45-day period following receipt of the written notice under 21 U.S.C. § 355(j)(5)(B)(iii).

27. Vanda received written notice of Apotex's ANDA and Paragraph IV Certification as to the '176 patent on December 10, 2019, along with an enclosed statement of Apotex's asserted factual and legal bases for stating that the claims of the '176 patent are invalid and/or will not be infringed by Apotex's ANDA Product. Vanda sued Apotex for infringing claims of the '176 patent on January 21, 2020, within the 45-day period following receipt of the written notice under 21 U.S.C. §355(j)(5)(B)(iii).

28. Vanda sued Apotex for infringing claims of the '511 patent on October 1, 2020, alleging that Apotex's ANDA Product infringed one or more claims of the '511 patent.

29. Vanda received written notice of Apotex's ANDA and Paragraph IV Certification as to the '465 patent on January 14, 2021, along with an enclosed statement of Apotex's asserted factual and legal bases for stating that the claims of the '465 patent, including claim 10, are invalid and/or that certain unasserted claims of the '465 patent will not be infringed by Apotex's ANDA Product. The Paragraph IV Certification did not provide any factual or legal bases for stating that claim 10 of the '465 patent will not be infringed by Apotex's ANDA Product. Vanda sued Apotex for infringing claims of the '465 patent on February 24, 2021, within the 45-day period following receipt of the written notice under 21 U.S.C. § 355(j)(5)(B)(iii).

III. THE ASSERTED PATENTS

1. The RE604 Patent

39. The RE604 patent is entitled "Treatment of Circadian Rhythm Disorders." The RE604 patent is a reissue of U.S. Patent No. 8,785,492 ("the '492 patent"), which was filed as U.S. Patent Application No. 15/051,978 ("the '978 application") with the U.S. Patent and Trademark Office ("USPTO") on February 24, 2016. The RE604 patent issued on November 14, 2017.

40. The priority date of claim 3 of the RE604 patent is January 26, 2012, the filing date of U.S. Provisional Patent Application No. 61/590,974.

41. The inventors of the RE604 patent are Marlene Michelle Dressman, John Joseph Feeney, Louis William Licamele, and Mihael H. Polymeropoulos.

42. Vanda is the record owner and sole assignee of all rights, title, and interests in the RE604 patent. Defendants do not contest Vanda's ownership, assignment, rights, or interests in the RE604 patent or Vanda's standing to assert the RE604 patent.

43. The expiration of the RE604 patent is January 25, 2033, which is stated in the Orange Book.

2. The '234 Patent

64. The '234 patent is entitled "Treatment of Circadian Rhythm Disorders." The '234 patent was filed as U.S. Patent Application No. 14/688,301 ("the '301 application"), which was filed with the USPTO on April 16, 2015. The '234 patent issued on January 10, 2017.

65. The '301 application is a division of the '799 application, now the '995 patent. The priority date of the '234 patent is October 15, 2012, which is the filing date of U.S. Provisional Patent Application No. 61/714,149.

66. The inventors of the '234 patent are Marlene Michelle Dressman, John Joseph Feeney, Louis William Licamele, and Mihael H. Polymeropoulos.

67. Vanda is the record owner and sole assignee of all rights, title, and interests in the '234 patent. Defendants do not contest Vanda's ownership, assignment, rights, or interests in the '234 patent or Vanda's standing to assert the '234 patent.

68. The expiration date of the '234 patent is January 25, 2033, which is stated in the Orange Book.

3. The '829 Patent

69. The '829 patent is entitled "Treatment of Circadian Rhythm Disorders." The '829 patent was filed as U.S. Patent Application No. 15/382,526 ("the '526 application"), which was filed with the USPTO on December 16, 2016. The '829 patent issued on December 11, 2018.

70. The '526 application is a continuation of the '301 application, now the '234 patent, which is a division of the '799 application, now the '995 patent. Like the '234 patent, the priority date of the '829 patent is October 15, 2012, the filing date of U.S. Provisional Patent Application No. 61/714,149.

71. The inventors of the '829 patent are Marlene Michelle Dressman, John Joseph Feeney, Louis William Licamele, and Mihael H. Polymeropoulos.

72. Vanda is the record owner and sole assignee of all rights, title, and interests in the '829 patent. Defendants do not contest Vanda's ownership,

assignment, rights, or interests in the '829 patent or Vanda's standing to assert the '829 patent.

73. The expiration date of the '829 patent is January 25, 2033, which is stated in the Orange Book.

4. The '910 Patent

74. The '910 patent is entitled "Treatment of Circadian Rhythm Disorders." The '910 patent was filed as U.S. Patent Application No. 14/510,321 ("the '321 application") was filed with the USPTO on October 9, 2014. The '910 patent issued on August 15, 2017.

75. The priority date of the '910 patent is November 12, 2013, the filing date of U.S. Provisional Patent Application No. 61/903,354.

76. The inventors of the '910 patent are Marlene Michelle Dressman, John Joseph Feeney, Louis William Licamele, and Mihael H. Polymeropoulos.

77. Vanda is the record owner and sole assignee of all rights, title, and interests in the '910 patent. Defendants do not contest Vanda's ownership, assignment, rights, or interests in the '910 patent or Vanda's standing to assert the '910 patent.

78. The expiration date of the '910 patent is May 17, 2034, which is stated in the Orange Book.

5. The '487 Patent

79. The '487 patent is entitled "Method of Treatment." The '487 patent was filed as U.S. Patent Application No. 14/511,669 ("the '669 application"), which was filed with the USPTO on October 10, 2014. The '487 patent issued on August 13, 2019.

80. The priority date of the '487 patent is November 12, 2013, the filing date of U.S. Provisional Patent Application No. 61/903,354, filed November 12, 2013.

81. The inventors of the '487 patent are Marlene Michelle Dressman, Mihael H. Polymeropoulos, and Paolo Baroldi.

82. Vanda is the record owner and sole assignee of all rights, title, and interests in the '487 patent. Defendants do not contest Vanda's ownership, assignment, rights, or interests in the '487 patent or Vanda's standing to assert the '487 patent.

83. The expiration date of the '487 patent is July 27, 2035, which is stated in the Orange Book.

6. The '465 Patent

89. The '465 patent is entitled "Highly Purified Pharmaceutical Grade Tasimelteon." The '465 patent was filed as U.S. Patent Application No. 16/800,721

(“the ’721 application”), which was filed with the USPTO on February 25, 2020. The ’465 patent issued on November 10, 2020.

90. The priority date of the ’465 patent is February 12, 2014, which is the filing date of U.S. Provisional Patent Application No. 61/938,932.

91. The inventors listed on the face of the ’465 patent are Deepak Phadke, Natalie M. Platt, and Ravi K. Pandrapragada.

92. Vanda is the record owner of the ’465 patent. Defendants do not contest Vanda’s standing to assert the ’465 patent.

93. The expiration date of the ’465 patent is February 12, 2035, which is stated in the Orange Book.

IV. CLAIM CONSTRUCTION

94. On October 29, 2019, the Court issued a claim construction order (D.I. 105), including constructions stipulated to by the parties and constructions adopted by the Court. On October 28, 2020, the Court issued a claim construction order (D.I. 183), including a construction stipulated to by the parties and constructions adopted by the Court. On May 3, 2021, the Court issued a claim construction order (D.I. 230), including constructions stipulated to by the parties and constructions adopted by the Court. The ordered constructions appear in the table below:

Claim Term	Court's Construction
<p>Claim preambles</p> <p>RE604 patent, claim 1 (from which asserted claim 3 depends); '234 patent, claim 1 (from which asserted claim 4 depends); '910 patent, claim 1 (from which asserted claim 4 depends); '829 patent, claim 13 (from which asserted claim 14 depends); '487 patent, claim 1 (from which asserted claim 5 depends)</p>	<p>The preambles are limiting.</p>
<p>“a daily sleep period of approximately 7 to 9 hours”</p> <p>RE604 patent, claim 1 (from which asserted claim 3 depends)</p>	<p>Plain and ordinary meaning.</p>
<p>“entraining a patient suffering from Non-24 to a 24 hour sleep-wake cycle in which the patient awakens at or near a target wake time following a daily sleep period of approximately 7 to 9 hours, and maintaining said 24 hour sleep-wake cycle”</p> <p>RE604 patent, claim 1 (from which asserted claim 3 depends)</p>	<p>“synchronizing a patient suffering from Non-24 to a 24-hour sleep-wake cycle in which the patient awakens at or near a target wake time following a daily sleep period of approximately 7 to 9 hours, and maintaining said 24 hour sleep-wake cycle during the course of treatment”</p>

Claim Term	Court's Construction
<p>“treating the patient by orally administering to the patient”</p> <p>RE604 patent, claim 1 (from which asserted claim 3 depends)</p>	<p>No construction necessary.</p>
<p>“treating the patient with tasimelteon”</p> <p>'234 patent, claim 1 (from which asserted claim 4 depends); '910 patent, claim 1 (from which asserted claim 4 depends)</p>	<p>No construction necessary.</p>
<p>“treating the patient with 20 mg of tasimelteon”</p> <p>'829 patent, claim 13 (from which asserted claim 14 depends)</p>	<p>No construction necessary.</p>
<p>“without food”</p> <p>'487 patent, claim 1 (from which asserted claim 5 depends)</p>	<p>“the patient has not consumed food within 30 minutes prior to administration of tasimelteon and does not consume food with the administration of tasimelteon.”</p>

V. FACTS PERTAINING TO INFRINGEMENT

95. Teva was aware of the RE604, '234, and '910 patents as of or before March 23, 2018. Teva was aware of the '829 patent as of or before February 7, 2019. Teva was aware of the '487 patent as of or before October 16, 2019. Teva was aware of the '465 patent as of or before December 18, 2020.

96. Apotex was aware of the RE604, '234, and '910 patents as of or before April 3, 2018. Apotex was aware of the '829 patent as of or before February 28, 2019. Apotex was aware of the '487 patent as of or before November 22, 2019. Apotex was aware of the '465 patent as of or before January 14, 2021.

97. As required by 21 C.F.R. § 314.94(a)(8)(iv), the language in Defendants' proposed labeling for each of their respective proposed ANDA products is essentially the same in all relevant aspects as Vanda's FDA-approved HETLIOZ[®] drug labeling. Differences in the language based on the fact that Defendants' ANDA product and Vanda's HETLIOZ[®] are produced and distributed by different manufacturers are not relevant to any claim or defense in this case. [REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED] but this language is not relevant to any claim or defense in this case.

98. If claim 5 of the '487 patent is not found invalid, Defendants will, by the use, sale, offer for sale, and importation into the United States of their ANDA

Products, induce infringement of claim 5 of the '487 patent pursuant to 35 U.S.C. § 271(e)(2)(A) and (b).¹

99. Each of Defendants' ANDA Products contain 20 mg of tasimelteon.

100. Each of Defendants' Labels states "[t]he recommended dosage of tasimelteon capsules in adults is 20 mg one hour before bedtime, at the same time every night."

101. Each of Defendants' Labels states that their respective ANDA Products "are indicated for the treatment of Non-24 in adults."

102. Fluvoxamine is a CYP1A2 inhibitor.

103. Rifampicin is a CYP3A4 inducer.

104. Each of Defendants' Labels states "[a]void use of tasimelteon in combination with fluvoxamine or other strong CYP1A2 inhibitors because of a potentially large increase in tasimelteon exposure and greater risk of adverse reactions."

105. Each of Defendants' Labels states "[a]void use of tasimelteon in combination with rifampin or other CYP3A4 inducers because of a potentially large decrease in tasimelteon exposure with reduced efficacy."

¹ For the avoidance of doubt, Defendants expressly reserve their right to challenge the validity of claims 1 and 5 of the '487 patent and claims 1 and 5 of the '511 patent at trial.

106. Tasimelteon is the only drug substance or active pharmaceutical ingredient in Vanda's HETLIOZ® drug product and in each of Defendants' ANDA Products.

107. After each of Defendants' tasimelteon drug substance is manufactured, it is not materially changed by any subsequent process(es), is not a trivial or nonessential component of Defendants' ANDA Products and does not become a trivial or nonessential component of another product.

108. After each of Defendants' ANDA Products is manufactured, it is not materially changed by any subsequent process(es) and does not become a trivial or nonessential component of another product.

109. Each of Defendants' tasimelteon drug substance and Defendants' ANDA Products is not a staple article or commodity of commerce.

VI. FACTS PERTAINING TO INVALIDITY

110. Chinese Patent Appl. No. CN 102675268 A ("CN '268"), titled "Method for Preparing ((1R,2R-2-(2,3-Dihydrobenzofuran-4-yl)cyclopropyl) methanamine," was publicly available at least as of September 19, 2012. Vanda does not dispute that this document was publicly available at least one year before the priority date of claim 10 of the '465 patent.

111. ICH Harmonized Tripartite Guideline, titled "Impurities in New Drug Substances Q3A(R2)" ("ICH Q3A Guideline"), was publicly available at least as of

October 25, 2006. Vanda does not dispute that this document was publicly available at least one year before the priority date of the Asserted Claims.

112. The publication titled “Factors Influencing the Application of Literature Methods Toward the Preparation of a Chiral *trans*-Cyclopropane Carboxylic Acid Intermediate During Development of a Melatonin Agonist,” authored by Ambarish K. Singh, et al. (“Singh 2004”), became publicly available in or around 2004. Vanda does not dispute that this document was publicly available at least one year before the priority date of the Asserted Claims.

113. U.S. Patent No. 5,856,529 (“529 patent”), titled “Benzofuran and Dihydrobenzofuran Melatonergic Agents,” issued, and became publicly available, as of January 5, 1999. Vanda does not dispute that this document was publicly available at least one year before the priority date of the Asserted Claims.

114. The publication titled “Tasimelteon for insomnia,” authored by Dr. Alan Lankford (“Lankford”), became publicly available on or around May 9, 2011. Vanda does not dispute that this document was publicly available before the priority date of the Asserted Claims.

115. The publication titled “The Effects of Low-Dose 0.5-mg Melatonin on the Free-Running Circadian Rhythms of Blind Subjects,” authored by Lisa M. Hack, et al. (“Hack”), became publicly available in or around October 2003. Vanda does

not dispute that this document was publicly available at least one year before the priority date of the Asserted Claims.

116. WO Patent No. 2007/137244 A1, titled “Melatonin Agonist Treatment” (“’244 Publication”), became publicly available on or around November 29, 2007. Vanda does not dispute that this document was publicly available at least one year before the priority date of the Asserted Claims.

117. The publication titled “New approaches in the management of insomnia: weighing the advantages of prolonged-release melatonin and synthetic melatoninergic agonists,” authored by Rudiger Hardeland (“Hardeland I”), became publicly in or around 2009. Vanda does not dispute that this document was publicly available at least one year before the priority date of the Asserted Claims.

118. The publication titled “Tasimelteon, a melatonin agonist for the treatment of insomnia and circadian rhythm sleep disorders,” authored by Rudiger Hardeland (“Hardeland II”), became publicly available on or around July 1, 2009. Vanda does not dispute that this document was publicly available at least one year before the priority date of the Asserted Claims.

119. The publication titled “Melatonin agonist tasimelteon (VEC-162) for transient insomnia after sleep-time shift: two randomized controlled multicenter trials,” authored by Shantha M.W. Rajaratnam, et al. (“Rajaratnam”), became publicly available on or around February 7, 2009. Vanda does not dispute that this

document was publicly available at least one year before the priority date of the Asserted Claims.

120. The publication titled “Cytochrome P450 and Drug Interactions,” authored by D.K. Badyal and A.P. Dadhich (“Badyal”), was publicly available in or around October 2001. Vanda does not dispute that this document was publicly available at least one year before the priority date of the Asserted Claims.

121. The publication titled “The Effect of Cytochrome P450 Metabolism on Drug Response, Interactions, and Adverse Effects,” authored by T. Lynch et al. (“Lynch”), became publicly available in or around August 2007. Vanda does not dispute that this document was publicly available at least one year before the priority date of the Asserted Claims.

122. The publication titled “Pharmacotherapy of Insomnia with Ramelteon: Safety, Efficacy and Clinical Applications,” authored by Seithikurippu R. Pandi-Perumal, et al. (“Pandi-Perumal”), became publicly available on or around April 12, 2011. Vanda does not dispute that this document was publicly available before the priority date of the Asserted Claims.

123. The publication titled “Metabolism of Ramelteon in Human Liver Microsomes and Correlation with the Effect of Fluvoxamine on Ramelteon Pharmacokinetics,” authored by R. Scott Obach and Tim F. Ryder (“Obach”), became publicly available in or around 2010. Vanda does not dispute that this

document was publicly available at least one year before the priority date of the Asserted Claims.

124. The term VEC-162 is a term that has been used to refer to tasimelteon.

125. The terms “BMS-214,778” and BMS-214778-01 have been used to refer to tasimelteon.

126. Fluvoxamine was a known strong CYP1A2 inhibitor prior to the filing date of the Asserted Patents.

127. Rifampicin was a known CYP3A4 inducer prior to the filing date of the Asserted Patents.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

VANDA PHARMACEUTICALS
INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA,
INC., et al.,

Defendants.

C.A. No. 18-651-CFC
(Consolidated)

Exhibit 2 – Plaintiff’s Statement of Contested Issues of Fact

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Plaintiff submits the following statement of contested issues of fact to be litigated at trial. This statement is based on Plaintiff's claims, Plaintiff's current understanding of Defendants' defenses and counterclaims, and the proceedings in this action to date. Plaintiff reserves the right to modify or amend this statement to the extent necessary to fairly respond to any new issues that Defendants may raise, if Defendants are permitted to raise new issues. Plaintiff further reserves the right to modify or amend this statement based upon the resolution of any outstanding motion or other future ruling by the Court. The following statements are not exhaustive and Plaintiff reserves the right to prove any matters identified in its pleadings, infringement contentions, written discovery responses, and/or expert reports. Plaintiff also intends to offer evidence as to the issues of fact and issues of law identified in this proposed joint pretrial order. Plaintiff further intends to offer evidence to rebut evidence offered by Defendants.

To the extent Plaintiff's Statement of Contested Issues of Law (Exhibit 4) contains issues of fact, those issues are incorporated by reference. To the extent this Statement of Contested Issues of Fact contains issues of law, those issues are incorporated by reference into Plaintiff's Statement of Contested Issues of Law. Plaintiff's statement includes for purposes of completeness certain legal issues raised by the parties' contentions without waiver of any argument regarding whether a particular issue is one of fact or law.

I. PERSON OF ORDINARY SKILL IN THE ART

1. Whether a person of ordinary skill in the art relevant to claim 3 of the RE604 patent is a person or persons or team of people with experience treating individuals with circadian rhythm disorders, including a person or persons or team of people qualified to prescribe medication, or a person or persons or team of people with experience researching circadian rhythm disorders.

2. Whether a person of ordinary skill in the art relevant to claim 4 of the '234 patent; claim 14 of the '829 patent; claim 4 of the '910 patent; claims 1 and 5 of the '487 patent; and claims 1 and 5 of the '511 patent is a person or persons or team of people having (1) a bachelor's degree and at least some laboratory experience in medicine, pharmacy, pharmacology, or a related field such as biochemistry, with experience with drug metabolism and/or drug-drug interactions, or at least some experience with preclinical and/or clinical drug development; and (2) experience treating individuals with circadian rhythm disorders, including a person or persons or team of people qualified to prescribe medication, or experience researching circadian rhythm disorders.

3. Whether a person of ordinary skill in the art relevant to claim 10 of the '465 patent is a person, persons, or team of people having a bachelor's degree in chemistry, organic chemistry, medicinal chemistry, chemical engineering, pharmaceuticals, or a related discipline.

II. PLAINTIFF'S CLAIMS

A. Induced Infringement of the Method-of-Treatment Patent Claims

4. Whether each Defendant is liable for induced infringement under 35 U.S.C. § 271(e)(2)(A) because they each submitted an ANDA to FDA for approval of a generic drug product (collectively, the “Proposed ANDA Products”) the use of which is covered by claim 3 of the **RE604** patent; claim 5 of the **'487** patent; claim 4 of the **'910** patent; claim 4 of the **'234** patent; and claim 14 of the **'829** patent (collectively, the “Asserted Method-of-Treatment Patent Claims”).

5. Whether each Defendant has the specific intent to induce infringement of the Asserted Method-of-Treatment Patent Claims.

6. Whether each Defendant's label for its Proposed ANDA Product (also known as “prescribing information” or “package insert”) encourages, recommends, promotes, suggests, instructs, teaches, and/or requires prescribers to practice any of the Asserted Method-of-Treatment Patent Claims.

7. Whether each Defendant's label for its Proposed ANDA Product demonstrates a specific intent to induce infringement of each of the Asserted Method-of-Treatment Patent Claims by encouraging, recommending, promoting, suggesting, instructing, teaching, and/or requiring prescribers to practice each of the Asserted Method-of-Treatment Patent Claims.

8. Whether prescribers administering tasimelteon according to each Defendant's label for its Proposed ANDA Product will inevitably lead to some prescribers practicing the method set forth in the Asserted Method-of-Treatment Patent Claims.

9. Whether the manufacture, use, offer for sale, sale, and/or importation of each Defendant's Proposed ANDA Product—when used according to the instructions provided in each Defendant's accompanying label before expiration of the Asserted Method-of-Treatment Patent Claims—will directly infringe any of the Asserted Method-of-Treatment Patent Claims under 35 U.S.C. § 271(a).

10. Whether the Defendants were aware of or relied upon the drafting history of the FDA-approved label for Hetlioz® in preparing their Proposed ANDA Products and their proposed labels for their Proposed ANDA Products.

B. Contributory Infringement of the Method-of-Treatment Patents

11. Whether each Defendant is liable for contributory infringement under 35 U.S.C. § 271(e)(2)(A) because it submitted an ANDA to FDA for approval of its Proposed ANDA Product, the use of which is covered by the Asserted Method-of-Treatment Patent Claims.

12. Whether each Defendant's Proposed ANDA Product, comprising the tasimelteon drug product and that Defendant's proposed label to accompany the sale,

marketing, and distribution of its tasimelteon drug product, constitutes material for use in practicing the Asserted Method-of-Treatment Patent Claims.

13. Whether each Defendant's Proposed ANDA Product and each Defendant's proposed label accompanying that Defendant's Proposed ANDA Product, together or individually, constitute a material part of the Asserted Method-of-Treatment Patent Claim inventions.

14. Whether each Defendant's Proposed ANDA Product and each Defendant's proposed label accompanying its Proposed ANDA Product, together or individually, have no substantial noninfringing use.

15. Whether each Defendant knows, and has known since at least the time of its ANDA filing, that its Proposed ANDA Product and its proposed label accompanying its Proposed ANDA Product, together or individually, are especially made or adapted for use in the infringement of the Asserted Method-of-Treatment Patent Claims.

16. Whether each Defendant's Proposed ANDA Product and each Defendant's proposed label accompanying its Proposed ANDA Product, together or individually, qualify as a staple article or commodity of commerce suitable for substantial noninfringing uses.

17. Whether the manufacture, use, offer for sale, sale, and/or importation of any of Defendants' Proposed ANDA Products—when used according to the

instructions provided in each Defendant’s accompanying label before expiration of the Asserted Method-of-Treatment Patent Claims—will directly infringe the Asserted Method-of-Treatment Patent Claims under 35 U.S.C. § 271(a).

C. Infringement of the Asserted Product-by-Process Patent Claim

18. Whether each Defendant is liable for direct infringement under 35 U.S.C. § 271(e)(2)(A) by submitting an ANDA to FDA for approval of its Proposed ANDA Product, the active pharmaceutical ingredient (“API”) of which is covered by claim 10 of the ’465 patent (the “Asserted Product-by-Process Patent Claim” and, together with the Asserted Method-of-Treatment Patent Claims, the “Asserted Claims”).

19. Whether each Defendant will make, use, sell, offer for sale, or import into the United States generic tasimelteon covered by the Asserted Product-by-Process Patent Claim upon final approval of its Proposed ANDA Product.

20. Whether each Defendant will import into the United States, or offer to sell, sell, or use generic tasimelteon within the United States that will be covered by the Asserted Product-by-Process Patent Claim upon final approval of its Proposed ANDA Product.

21. Whether each Defendant’s generic tasimelteon is manufactured under the direction and control of that Defendant and as part of a joint enterprise with that Defendant.

D. Additional Claims

22. Whether this is an “exceptional” case pursuant to 35 U.S.C. § 285.

E. Relief

23. Whether Plaintiff is entitled to an order that the effective date of any approval of each Defendant’s Proposed ANDA Product be a date that is not earlier than the date of the expiration of the patent(s) that have been infringed.

24. Whether Plaintiff is entitled to injunctive relief against each Defendant to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of that Defendant’s Proposed ANDA Product prior to date of the expiration of the patent(s) that have been infringed.

III. DEFENDANTS’ CLAIMS¹

A. Invalidity, Generally

25. Whether Defendants have satisfied their burden of proving that the Asserted Claims, and claim 1 of the ’487 patent, and claims 1 and 5 of the ’511 patent are invalid by clear and convincing evidence.

26. Whether Defendants have overcome the added burden of proving that the Asserted Claims, claim 1 of the ’487 patent, and claims 1 and 5 of the ’511 patent

¹ Plaintiff is not aware of any factual disputes related to Defendants’ invalidity challenges to claims no longer asserted in this litigation and thus have not addressed them here. Plaintiff reserves the right to amend its Statement of Contested Issues of Fact to address such invalidity challenges if Defendants seek to maintain them at trial.

are anticipated or obvious based on alleged prior art references that were before the U.S. Patent and Trademark Office.

27. Whether Defendants have proven by clear and convincing evidence that each of the Alleged Prior Art² qualifies as prior art under 35 U.S.C. § 102.

28. Whether Defendants have proven by clear and convincing evidence that each of the Alleged Prior Art was accessible by members of the relevant public as of the priority date for the Asserted Claims, claims 1 of the '487 patent, and claims 1 and 5 of the '511 patent.

B. Anticipation

29. Whether Defendants have proven by clear and convincing evidence that the Asserted Claims, claim 1 of the '487 patent, and claims 1 and 5 of the '511 patent are anticipated.

30. Whether Defendants have proven by clear and convincing evidence that each of the Alleged Prior Art disclose, expressly or inherently, each and every element of the Asserted Claims, claim 1 of the '487 patent, and claims 1 and 5 of the '511 patent.

² "Alleged Prior Art" refers to the prior art references identified in Defendants' Statement of Contested Issues of Fact (Exhibit 3), ¶¶ 32-34, 47-48, 51, 55-56, 61-62, 67-68, 73-74, 77-80, 86-87, 90-93, which are CN '268, ICH Q3A Guideline, Singh, the '529 patent, Clinical Trials, Lankford, Hack, '244 publication, Hardeland, Rajaratnam, Badyal, Lynch, Pandi-Perumal, Obach.

31. Whether Defendants have proven by clear and convincing evidence each and every allegedly inherent element of each of the Alleged Prior Art is necessarily and inevitably present in the respective Alleged Prior Art.

32. Whether the each of the Alleged Prior Art asserted by Defendants for anticipation contains an enabling disclosure.

33. Whether a person of ordinary skill in the art would be able to practice the claimed subject matter of the Asserted Claims, claim 1 of the '487 patent, and claims 1 and 5 of the '511 patent by performing what is allegedly disclosed in the each of the Alleged Prior Art without undue experimentation.

34. Whether Defendants have proven by clear and convincing evidence that the subject matter of claim 10 of the '465 patent was the subject of a commercial offer for sale and was ready for patenting at the time of the alleged offer for sale.

35. Whether Defendants have proven by clear and convincing evidence that the entire claimed invention of claim 10 was on sale.

36. Whether Defendants have proven by clear and convincing evidence that [REDACTED] [REDACTED] establish the occurrence of a sale of the entire invention claimed by claim 10 of the '465 patent.

37. Whether any alleged sale or offer for sale of the subject matter of claim 10 of the '465 patent was confidential.

38. Whether any alleged sale of [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

39. Whether any alleged sale or offer for sale, of the subject matter of the Asserted Claims was for the purpose of experimentation or qualified as an experimental use.

40. Whether any alleged sale or offer for sale of the subject matter of the Asserted Claims occurred as a means of furthering research.

41. Whether Defendants' asserted Clinical Trials reflects the experimental use of the subject matter of the Asserted Claims.

42. Whether Clinical Trials discloses experimentation designed to determine if it would be possible to treat Non-24-Hour Sleep-Wake Disorder with tasimelteon under certain conditions, and does not discloses the actual treatment of Non-24-Hour Sleep-Wake Disorder with tasimelteon under certain conditions.

43. Whether Clinical Trials describes a non-Phase I clinical investigation that was subject to Section 505 of the FD&C Act.

44. Whether Vanda was required by law to submit its initial clinical trial study design and subsequent updates, including Clinical Trials, for public posting on clinicaltrials.gov.

45. Whether Defendants have proven by clear and convincing evidence that each of the Alleged Prior Art qualifies as prior art.

46. Whether Defendants have proven by clear and convincing evidence that each of the Alleged Prior Art was accessible by members of the relevant public as of the priority date for the applicable Asserted Claims, claim 1 of the '487 patent, and claims 1 and 5 of the '511 patent.

47. Whether Defendants have proven by clear and convincing evidence that Clinical Trials qualifies as prior art.

48. Whether Defendants have proven by clear and convincing evidence that Clinical Trials was accessible by members of the relevant public as of the priority date for the applicable Asserted Claims, claim 1 of the '487 patent, and claims 1 and 5 of the '511 patent.

49. Whether Defendants have proven by clear and convincing evidence that Clinical Trials anticipates claim 3 of the RE604 patent.

50. Whether Defendants have proven by clear and convincing evidence that Clinical Trials anticipates claims 1 and 5 of the '487 patent.

51. Whether Defendants have proven by clear and convincing evidence that Lankford anticipates claims 1 and 5 of the '487 patent.

52. Whether Defendants have proven by clear and convincing evidence that the '244 Publication anticipates claim 1 of the '487 patent.

53. Whether Defendants have proven by clear and convincing evidence that Hardeland anticipates claim 1 of the '487 patent.

54. Whether Defendants have proven by clear and convincing evidence that Clinical Trials anticipates claims 1 and 5 of the '511 patent.

55. Whether Defendants have proven by clear and convincing evidence that Lankford anticipates claims 1 and 5 of the '511 patent.

56. Whether Defendants have proven by clear and convincing evidence that the '244 Publication anticipates claims 1 and 5 of the '511 patent.

57. Whether Defendants have proven by clear and convincing evidence that Hardeland anticipates claims 1 and 5 of the '511 patent.

C. Obviousness

58. Whether Defendants have proven by clear and convincing evidence that the Asserted Claims, claim 1 of the '487 patent, and claims 1 and 5 of the '511 patent are obvious.

59. Whether Defendants have met their burden of proof as to each of the *Graham* factors.

60. Whether Defendants have established the scope and content of the prior art by clear and convincing evidence.

61. Whether Defendants have established by clear and convincing evidence that any differences between the prior art and the Asserted Claims, claim 1 of the '487 patent, and claims 1 and 5 of the '511 patent were trivial, insignificant, or otherwise sufficiently minor so as to permit a person of no more than ordinary skill in the relevant art to make the claimed inventions.

62. Whether Defendants have proven by clear and convincing evidence that the Alleged Prior Art are analogous art for the Asserted Claims, claim 1 of the '487 patent, and claims 1 and 5 of the '511 patent.

63. Whether Defendants have proven by clear and convincing evidence that each of the Alleged Prior Art qualifies as prior art.

64. Whether Defendants have proven by clear and convincing evidence that each of the Alleged Prior Art was accessible by members of the relevant public as of the priority date for the Asserted Claims, claim 1 of the '487 patent, and claims 1 and 5 of the '511 patent.

65. Whether Defendants have proven by clear and convincing evidence that Clinical Trials qualifies as prior art.

66. Whether Defendants have proven by clear and convincing evidence that Clinical Trials was accessible by members of the relevant public as of the priority

date of the applicable Asserted Claims, claim 1 of the '487 patent, and claims 1 and 5 of the '511 patent.

67. Whether Defendants have proven by clear and convincing evidence that the teachings of CN '268 in view of ICH Q3A Guideline disclose or render obvious all of the limitations of claim 10 of the '465 patent, and that a person of ordinary skill in the art as of the priority date of claim 10 of the '465 patent would have been motivated to combine the teachings of CN '268 in view of ICH Q3A Guideline and, separately, that a person of ordinary skill in the art would have had a reasonable expectation of successfully achieving claim 10 of the '465 patent in doing so.

68. Whether Defendants have proven by clear and convincing evidence that the teachings of Singh in view of ICH Q3A Guideline disclose or render obvious all of the limitations of claim 10 of the '465 patent, and that a person of ordinary skill in the art as of the priority date of claim 10 of the '465 patent would have been motivated to combine the teachings of Singh in view of ICH Q3A Guideline and, separately, that a person of ordinary skill in the art would have had a reasonable expectation of successfully achieving claim 10 of the '465 patent in doing so.

69. Whether Defendants have proven by clear and convincing evidence that the teachings of '529 patent in view of ICH Q3A Guideline disclose or render obvious all of the limitations of claim 10 of the '465 patent, and that a person of ordinary skill in the art as of the priority date of claim 10 of the '465 patent would

have been motivated to combine the teachings of the '529 patent in view of ICH Q3A Guideline and, separately, that a person of ordinary skill in the art would have had a reasonable expectation of successfully achieving claim 10 of the '465 patent in doing so.

70. Whether Defendants have proven by clear and convincing evidence that the teachings of Clinical Trials, Lankford, Hack, and '244 publication disclose or render obvious all of the limitations of claim 3 of the RE604 patent, and that a person of ordinary skill in the art as of the priority date of claim 3 of the RE604 patent would have been motivated to combine the teachings of Clinical Trials, Lankford, Hack, and '244 publication and, separately, that a person of ordinary skill in the art would have had a reasonable expectation of successfully achieving claim 3 of the RE604 patent in doing so.

71. Whether Defendants have proven by clear and convincing evidence that the teachings of '244 publication, Hardeland, Hack, and Rajaratnam disclose or render obvious all of the limitations of claim 3 of the RE604 patent, and that a person of ordinary skill in the art as of the priority date of claim 3 of the RE604 patent would have been motivated to combine the teachings of '244 publication, Hardeland, Hack, and Rajaratnam and, separately, that a person of ordinary skill in the art would have had a reasonable expectation of successfully achieving claim 3 of the RE604 patent in doing so.

72. Whether Defendants have proven by clear and convincing evidence that the teachings of Clinical Trials, Lankford, Hack, '244 publication, Hardeland, Badyal, and Lynch disclose or render obvious all of the limitations of claim 4 of the '234 patent, and that a person of ordinary skill in the art as of the priority date of claim 4 of the '234 patent would have been motivated to combine the teachings of Clinical Trials, Lankford, Hack, '244 publication, Hardeland, Badyal, and Lynch and, separately, that a person of ordinary skill in the art would have had a reasonable expectation of successfully achieving claim 4 of the '234 patent in doing so.

73. Whether Defendants have proven by clear and convincing evidence that the teachings of '244 publication, Hardeland, Hack, Rajaratnam, Badyal, and Lynch disclose or render obvious all of the limitations of claim 4 of the '234 patent, and that a person of ordinary skill in the art as of the priority date of claim 4 of the '234 patent would have been motivated to combine the teachings of '244 publication, Hardeland, Hack, Rajaratnam, Badyal, and Lynch and, separately, that a person of ordinary skill in the art would have had a reasonable expectation of successfully achieving claim 4 of the '234 patent in doing so.

74. Whether Defendants have proven by clear and convincing evidence that the teachings of Clinical Trials, Lankford, Hack, '244 publication, Hardeland, Pandi-Perumal, and Obach disclose or render obvious all of the limitations of

claim 4 of the '910 patent, and that a person of ordinary skill in the art as of the priority date of claim 4 of the '910 patent would have been motivated to combine the teachings of Clinical Trials, Lankford, Hack, '244 publication, Hardeland, Pandi-Perumal, and Obach and, separately, that a person of ordinary skill in the art would have had a reasonable expectation of successfully achieving claim 4 of the '910 patent in doing so.

75. Whether Defendants have proven by clear and convincing evidence that the teachings of '244 publication, Hardeland, Hack, Rajaratnam, Pandi-Perumal, and Obach disclose or render obvious all of the limitations of claim 4 of the '910 patent, and that a person of ordinary skill in the art as of the priority date of claim 4 of the '910 patent would have been motivated to combine the teachings of '244 publication, Hardeland, Hack, Rajaratnam, Pandi-Perumal, and Obach and, separately, that a person of ordinary skill in the art would have had a reasonable expectation of successfully achieving claim 4 of the '910 patent in doing so.

76. Whether Defendants have proven by clear and convincing evidence that the teachings of Clinical Trials, Lankford, Hack, '244 publication, Hardeland, Badyal, and Lynch disclose or render obvious all of the limitations of claim 14 of the '829 patent, and that a person of ordinary skill in the art as of the priority date of claim 14 of the '829 patent would have been motivated to combine the teachings of Clinical Trials, Lankford, Hack, '244 publication, Hardeland, Badyal, and Lynch

and, separately, that a person of ordinary skill in the art would have had a reasonable expectation of successfully achieving claim 14 of the '829 patent in doing so.

77. Whether Defendants have proven by clear and convincing evidence that the teachings of '244 publication, Hardeland, Hack, Rajaratnam, Badyal, and Lynch disclose or render obvious all of the limitations of claim 14 of the '829 patent, and that a person of ordinary skill in the art as of the priority date of claim 14 of the '829 patent would have been motivated to combine the teachings of '244 publication, Hardeland, Hack, Rajaratnam, Badyal, and Lynch and, separately, that a person of ordinary skill in the art would have had a reasonable expectation of successfully achieving claim 14 of the '829 patent in doing so.

78. Whether Defendants have proven by clear and convincing evidence that the teachings of Clinical Trials, Lankford, Hack, and '244 publication disclose or render obvious all of the limitations of claims 1 and 5 of the '487 patent, and that a person of ordinary skill in the art as of the priority date of claims 1 and 5 of the '487 patent would have been motivated to combine the teachings of Clinical Trials, Lankford, Hack, and '244 publication and, separately, that a person of ordinary skill in the art would have had a reasonable expectation of successfully achieving claims 1 and 5 of the '487 patent in doing so.

79. Whether Defendants have proven by clear and convincing evidence that the teachings of '244 publication, Hardeland, Hack, and Rajaratnam disclose or

render obvious all of the limitations of claims 1 and 5 of the '487 patent, and that a person of ordinary skill in the art as of the priority date of claims 1 and 5 of the '487 patent would have been motivated to combine the teachings of '244 publication, Hardeland, Hack, and Rajaratnam and, separately, that a person of ordinary skill in the art would have had a reasonable expectation of successfully achieving claims 1 and 5 of the '487 patent in doing so.

80. Whether Defendants have proven by clear and convincing evidence that the teachings of Clinical Trials, Lankford, Hack, and '244 publication disclose or render obvious all of the limitations of claims 1 and 5 of the '511 patent, and that a person of ordinary skill in the art as of the priority date of claims 1 and 5 of the '511 patent would have been motivated to combine the teachings of Clinical Trials, Lankford, Hack, and '244 publication and, separately, that a person of ordinary skill in the art would have had a reasonable expectation of successfully achieving claims 1 and 5 of the '511 patent in doing so.

81. Whether Defendants have proven by clear and convincing evidence that the teachings of '244 publication, Hardeland, Hack, and Rajaratnam disclose or render obvious all of the limitations of claims 1 and 5 of the '511 patent, and that a person of ordinary skill in the art as of the priority date of claims 1 and 5 of the '511 patent would have been motivated to combine the teachings of '244 publication, Hardeland, Hack, and Rajaratnam and, separately, that a person of ordinary skill in

the art would have had a reasonable expectation of successfully achieving claims 1 and 5 of the '511 patent in doing so.

82. Whether Defendants' obviousness challenges are informed by hindsight.

83. Whether the prior art taught away from the Asserted Claims, claims 1 of the '487 patent, and claims 1 and 5 of the '511 patent.

D. Secondary Considerations for the Asserted Method-of-Treatment Patent Claims

84. Whether Hetlioz[®] is a commercial success.

85. Whether Hetlioz[®] is [REDACTED] in excess of the average return that a pharmaceutical company can expect to attain through an alternative investment, and that [REDACTED] are causally related to the embodiment of the claimed inventions rather than to companion factors, such as advertising or attractive packaging.

86. Whether the embodiments of the Asserted Method-of-Treatment Patent Claims, claim 1 of the '487 patent, and claims 1 and 5 of the '511 patent fulfilled a previously long-felt, unmet need.

87. Whether the embodiments of the Asserted Method-of-Treatment Patent Claims, claim 1 of the '487 patent, and claims 1 and 5 of the '511 patent have received industry praise.

88. Whether others in the industry had tried and failed to develop the inventions described by the Asserted Method-of-Treatment Patent Claims, claim 1 of the '487 patent, and claims 1 and 5 of the '511 patent.

89. Whether others in the industry were skeptical of the inventions described in the Asserted Method-of-Treatment Patent Claims, claim 1 of the '487 patent, and claims 1 and 5 of the '511 patent.

90. Whether the Asserted Method-of-Treatment Patent Claims, claim 1 of the '487 patent, and claims 1 and 5 of the '511 patent achieved unexpected results.

91. Whether the technical direction followed by those of ordinary skill in the art at the time of the priority dates of the Asserted Method-of-Treatment Patent Claims, claim 1 of the '487 patent, and claims 1 and 5 of the '511 patent taught away from the Asserted Method-of-Treatment Patent Claims, claim 1 of the '487 patent, and claims 1 and 5 of the '511 patent.

92. Whether each of the Asserted Method-of-Treatment Patent Claims, claim 1 of the '487 patent, and claims 1 and 5 of the '511 patent is embodied by the Hetlitz[®] product, such that there is a nexus between Plaintiff's asserted objective indicia of nonobviousness and the Asserted Method-of-Treatment Patent Claims, claim 1 of the '487 patent, and claims 1 and 5 of the '511 patent.

93. Whether Hetlitz[®] embodies the claimed features of the Asserted Method-of-Treatment Patent Claims, claim 1 of the '487 patent, and claims 1 and 5

of the '511 patent, and is coextensive with these claimed features, such that a nexus should be presumed and the burden of presenting evidence to rebut this presumed nexus has shifted to Defendants.

94. Whether Defendants have proven by clear and convincing evidence that a blocking patent existed that would reduce the probative value of commercial success, failure of others, or long-felt but unmet need.

E. Secondary Considerations for the Asserted Product-by-Process Patent Claim

95. Whether the embodiments of the Asserted Product-by-Process Patent Claim fulfilled a previously long-felt, unmet need.

96. Whether the Asserted Product-by-Process Patent Claim achieved unexpected results.

97. Whether others in the industry failed to recognize the impurity issues and identify the claimed impurities or develop the inventions described by the Asserted Product-by-Process Patent Claim.

98. Whether the Asserted Product-by-Process Patent Claim is embodied by the Hetlioz[®] product, such that there is a nexus between Plaintiff's asserted objective indicia of nonobviousness and the Asserted Product-by-Process Patent Claim.

F. Written Description

99. Whether Defendants have proven by clear and convincing evidence that claim 1 of the '511 patent lacks written description support.

100. Whether Defendants have proven by clear and convincing evidence that claim 1 of the '487 patent lacks written description support.

G. Enablement

101. Whether Defendants have proven by clear and convincing evidence that claim 1 of the '511 patent is not enabled.

102. Whether Defendants have proven by clear and convincing evidence that claim 1 of the '487 patent is not enabled.

H. Improper Inventorship

103. Whether Defendants have proven by clear and convincing evidence that the product and process limitations of claim 10 of the '465 patent were conceived of by someone other than the named inventors.

104. Whether Defendants have proven by clear and convincing evidence that someone other than the named inventors conceived of each and every element of claim 10 of the '465 patent, including the claimed product and the claimed process steps.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

VANDA PHARMACEUTICALS INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA,
INC., et al.,

Defendants.

C.A. No. 18-651-CFC
(Consolidated)

**EXHIBIT 3 – DEFENDANTS’ STATEMENT
OF CONTESTED ISSUES OF FACT**

Defendants Apotex Inc. and Apotex Corp. (collectively, “Apotex”) and Teva Pharmaceuticals, USA, Inc. identify the following issues of fact that remain to be litigated, which is based on Defendants’ claims and Defendants’ current understanding of Plaintiff’s claims and the proceedings in this action to date. If Plaintiff seeks to introduce different arguments, Defendants reserve the right to supplement this statement. To the extent Defendants’ Statement of Issues of Law contains issues of fact, those issues are incorporated herein by reference. Likewise, should the Court determine that any issue identified below is more appropriately considered an issue of law, Defendants incorporate such issues by reference into their Statement of Issues of Law.

By including a fact herein, Defendants do not assume the burden of proof or production with regard to that fact. Nor do Defendants concede that any genuine factual dispute exists as to any of the issues listed below. Defendants reserve the right to revise this statement in light of the Court’s rulings, in response to Plaintiff’s positions, or as otherwise may be appropriate. The following statements are not exhaustive, and Defendants reserve the right to prove any matters identified in their pleadings, contentions, interrogatory responses, and/or expert reports. Defendants also intend to offer evidence as to the issues of fact and issues of law identified in this pretrial order. Defendants further intend to offer evidence to rebut evidence offered by Plaintiff and to argue that Plaintiff is precluded from offering

evidence in support of theories and claims not adequately disclosed in accordance with the scheduling order. Defendants incorporate by reference their expert reports in support of any proof to be presented by expert testimony.

The following issues of fact remain to be litigated.

I. NON-INFRINGEMENT OF THE '465 PATENT

1. Whether Plaintiff has proven by a preponderance of the evidence that Teva's submission to the FDA of ANDA No. 211601 ("Teva's ANDA") was an act of infringement of claim 10 of U.S. Patent No. 10,829,465.

2. Whether Plaintiff has proven by a preponderance of the evidence that the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of the proposed drug product described in Teva's ANDA ("Teva's ANDA Product") will infringe claim 10 of the '465 patent.

3. Whether Plaintiff has proven by a preponderance of the evidence that Teva will induce infringement of claim 10 of the '465 patent by others, such as [REDACTED], under 35 U.S.C. § 271(b).

4. Whether Plaintiff has proven by a preponderance of the evidence that Teva will contribute to the direct infringement of claim 10 of the '465 patent by [REDACTED], under 35 U.S.C. § 271(c).

5. Whether Plaintiff has proven by a preponderance of the evidence that it has suffered or would suffer irreparable harm, not compensable by remedies available at law, from the approval of Teva's ANDA Product.

6. Whether Plaintiff has proven by a preponderance of the evidence that it is entitled to any injunctive relief.

7. To the extent Teva commercializes its product, whether Plaintiff has proven by a preponderance of the evidence that it is entitled to damages under 35 U.S.C. § 284.

8. Whether Plaintiff has proven by a preponderance of the evidence that Apotex's submission to the FDA of ANDA No. 211607 ("Apotex's ANDA") was an act of infringement of claim 10 of the '465 patent.

9. Whether Plaintiff has proven by a preponderance of the evidence that the manufacture, use, offer for sale, marketing, distribution and/or importation of the proposed drug product described in Apotex's ANDA ("Apotex's ANDA Product") will infringe claim 10 of the '465 patent.

10. Whether Plaintiff has proven by a preponderance of the evidence that the manufacture, use, offer for sale, marketing, distribution and/or importation of Apotex's ANDA Product will induce infringement of claim 10 of the '465 patent by others, under 35 U.S.C. § 271(b).

11. Whether Plaintiff has proven by a preponderance of the evidence that the manufacture, use, offer for sale, marketing, distribution and/or importation of Apotex's ANDA Product will contribute to the direct infringement of claim 10 of the '465 patent under 35 U.S.C. § 271(c).

12. Whether Plaintiff has proven by a preponderance of the evidence that it has suffered or would suffer irreparable harm, not compensable by remedies available at law, from the approval of Apotex's ANDA Product.

13. Whether Plaintiff has proven by a preponderance of the evidence that it is entitled to any injunctive relief.

14. To the extent Apotex commercializes its product, whether Plaintiff has proven by a preponderance of the evidence that it is entitled to damages under 35 U.S.C. § 284.

II. NON-INFRINGEMENT OF THE METHOD-OF-TREATMENT PATENTS

15. Whether Plaintiff has proven by a preponderance of the evidence that Teva's submission to the FDA of Teva's ANDA was an act of infringement of claim 3 of U.S. Patent No. RE46,604; claim 4 of U.S. Patent No. 9,539,234; claim 14 of U.S. Patent No. 10,149,829; and claim 4 of U.S. Patent No. 9,730,910.

16. Whether Plaintiff has proven by a preponderance of the evidence that the submission of Apotex's ANDA to the FDA was an act of infringement of claim 3 of U.S. Patent No. RE46,604; claim 4 of U.S. Patent No. 9,539,234; claim 14 of U.S. Patent No. 10,149,829; and claim 4 of U.S. Patent No. 9,730,910.

17. Whether Plaintiff has proven by a preponderance of the evidence that the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Teva's ANDA Product will infringe claim 3 of U.S. Patent No. RE46,604; claim

4 of U.S. Patent No. 9,539,234; claim 14 of U.S. Patent No. 10,149,829; and claim 4 of U.S. Patent No. 9,730,910.

18. Whether Plaintiff has proven by a preponderance of the evidence that the manufacture, use, offer for sale, marketing, distribution and/or importation of Apotex's ANDA Product will infringe claim 3 of U.S. Patent No. RE46,604; claim 4 of U.S. Patent No. 9,539,234; claim 14 of U.S. Patent No. 10,149,829; and claim 4 of U.S. Patent No. 9,730,910.

19. Whether Plaintiff has proven by a preponderance of the evidence that Teva will induce infringement of claim 3 of U.S. Patent No. RE46,604; claim 4 of U.S. Patent No. 9,539,234; claim 14 of U.S. Patent No. 10,149,829; and claim 4 of U.S. Patent No. 9,730,910 by patients and healthcare providers, under 35 U.S.C. § 271(b).

20. Whether Plaintiff has proven by a preponderance of the evidence that Apotex will induce infringement of claim 3 of U.S. Patent No. RE46,604; claim 4 of U.S. Patent No. 9,539,234; claim 14 of U.S. Patent No. 10,149,829; and claim 4 of U.S. Patent No. 9,730,910 by patients and healthcare providers, under 35 U.S.C. § 271(b).

21. Whether Plaintiff has proven by a preponderance of the evidence that Teva will contribute to the direct infringement of claim 3 of U.S. Patent No. RE46,604; claim 4 of U.S. Patent No. 9,539,234; claim 14 of U.S. Patent No. 10,149,829; and claim 4 of U.S. Patent No. 9,730,910 by patients and healthcare providers, under 35 U.S.C. § 271(c).

22. Whether Plaintiff has proven by a preponderance of the evidence that Apotex will contribute to the direct infringement of claim 3 of U.S. Patent No. RE46,604; claim 4 of U.S. Patent No. 9,539,234; claim 14 of U.S. Patent No. 10,149,829; and claim 4 of U.S. Patent No. 9,730,910 by patients and healthcare providers, under 35 U.S.C. § 271(c).

23. Whether Plaintiff has proven by a preponderance of the evidence that it has suffered or would suffer irreparable harm, not compensable by remedies available at law, from the approval of Teva's ANDA Product.

24. Whether Plaintiff has proven by a preponderance of the evidence that it has suffered or would suffer irreparable harm, not compensable by remedies available at law, from the approval of Apotex's ANDA Product.

25. Whether Plaintiff has proven by a preponderance of the evidence that it is entitled to any injunctive relief.

26. To the extent Teva commercializes its product, whether Plaintiff has proven by a preponderance of the evidence that it is entitled to damages under 35 U.S.C. § 284.

27. To the extent Apotex commercializes its product, whether Plaintiff has proven by a preponderance of the evidence that it is entitled to damages under 35 U.S.C. § 284.

28. Whether Plaintiff has proven by a preponderance of the evidence that this case is exceptional and it is entitled to attorney's fees pursuant to 35 U.S.C. § 285.

III. INVALIDITY OF THE '465 PATENT

29. The qualifications and knowledge of a person of ordinary skill in the art pertinent to claim 10 of U.S. Patent No. 10,829,465 as of the priority date.

30. The scope and content of the prior art and differences (if any) between the claimed inventions of the '465 patent and the prior art.

31. Whether claim 10 of the '465 patent is invalid under 35 U.S.C. § 103 as obvious.

32. Whether claim 10 of the '465 patent is invalid under 35 U.S.C. § 103 as obvious over CN '268 in view of ICH Q3A Guideline.

33. Whether claim 10 of the '465 patent is invalid under 35 U.S.C. § 103 as obvious over Singh in view of ICH Q3A Guideline.

34. Whether claim 10 of the '465 patent is invalid under 35 U.S.C. § 103 as obvious over the '529 patent in view of ICH Q3A Guideline.

35. Whether Plaintiff has shown that secondary considerations of nonobviousness support a non-obviousness finding and have a nexus to claim 10 of the '465 patent.

36. Whether claim 10 of the '465 patent is invalid under 35 U.S.C. § 102 as anticipated.

37. Whether claim 10 of the '465 patent is invalid pursuant to 35 U.S.C. § 102 for the offer for sale, sale, and use of tasimelteon [REDACTED]

38. Whether Plaintiff has shown that the offer for sale, sale, and use of tasimelteon [REDACTED] was for experimental use.

39. Whether claim 10 of the '465 patent is invalid pursuant to 35 U.S.C. § 102 for the offer for sale, sale, and use of tasimelteon [REDACTED].

40. Whether Plaintiff has shown that the offer for sale, sale, and use of tasimelteon [REDACTED] was for experimental use.

41. Whether claim 10 of the '465 patent is invalid pursuant to 35 U.S.C. § 102 for the offer for sale, sale, and use of tasimelteon under [REDACTED].

42. Whether Plaintiff has shown that the offer for sale, sale, and use of tasimelteon under [REDACTED] was for experimental use.

43. Whether claim 10 of the '465 patent is invalid under 35 U.S.C. § 101 and/or § 115 for improper inventorship.

IV. INVALIDITY OF THE '604 PATENT

44. The qualifications and knowledge of a person of ordinary skill in the art pertinent to claim 3 of U.S. Patent No. RE46,604 as of the priority date.

45. The scope and content of the prior art and differences (if any) between the claimed inventions of the '604 patent and the prior art.

46. Whether claim 3 of the '604 patent is invalid under 35 U.S.C. § 103 as obvious.

47. Whether claim 3 of the '604 patent is invalid under 35 U.S.C. § 103 as obvious over Clinical Trials, Lankford, Hack, and '244 publication.

48. Whether claim 3 of the '604 patent is invalid under 35 U.S.C. § 103 as obvious over '244 publication, Hardeland, Hack, and Rajaratnam.

49. Whether Plaintiff has shown that secondary considerations of nonobviousness support a non-obviousness finding and have a nexus to claim 3 of the '604 patent.

50. Whether claim 3 of the '604 patent is invalid under 35 U.S.C. § 102 as anticipated.

51. Whether claim 3 of the '604 patent is invalid under 35 U.S.C. § 102 as anticipated by Clinical Trials.

V. INVALIDITY OF THE '234 PATENT

52. The qualifications and knowledge of a person of ordinary skill in the art pertinent to claim 4 of U.S. Patent No. 9,539,234 as of the priority date.

53. The scope and content of the prior art and differences (if any) between the claimed inventions of the '234 patent and the prior art.

54. Whether claim 4 of the '234 patent is invalid under 35 U.S.C. § 103 as obvious.

55. Whether claim 4 of the '234 patent is invalid under 35 U.S.C. § 103 as obvious over Clinical Trials, Lankford, Hack, '244 publication, Hardeland, Badyal, and Lynch.

56. Whether claim 4 of the '234 patent is invalid under 35 U.S.C. § 103 as obvious over '244 publication, Hardeland, Hack, Rajaratnam, Badyal, and Lynch.

57. Whether Plaintiff has shown that secondary considerations of nonobviousness support a non-obviousness finding and have a nexus to claim 4 of the '234 patent.

VI. INVALIDITY OF THE '910 PATENT

58. The qualifications and knowledge of a person of ordinary skill in the art pertinent to claim 4 of U.S. Patent No. 9,730,910 as of the priority date.

59. The scope and content of the prior art and differences (if any) between the claimed inventions of the '910 patent and the prior art.

60. Whether claim 4 of the '910 patent is invalid under 35 U.S.C. § 103 as obvious.

61. Whether claim 4 of the '910 patent is invalid under 35 U.S.C. § 103 as obvious over Clinical Trials, Lankford, Hack, and '244 publication, Hardeland, Pandi-Perumal, and Obach.

62. Whether claim 4 of the '910 patent is invalid under 35 U.S.C. § 103 as obvious over '244 publication, Hardeland, Hack, Rajaratnam, Pandi-Perumal, and Obach.

63. Whether Plaintiff has shown that secondary considerations of nonobviousness support a non-obviousness finding and have a nexus to claim 4 of the '910 patent.

VII. INVALIDITY OF THE '829 PATENT

64. The qualifications and knowledge of a person of ordinary skill in the art pertinent to claim 14 of U.S. Patent No. 10,149,829 as of the priority date.

65. The scope and content of the prior art and differences (if any) between the claimed inventions of the '829 patent and the prior art.

66. Whether claim 14 of the '829 patent is invalid under 35 U.S.C. § 103 as obvious.

67. Whether claim 14 of the '829 patent is invalid under 35 U.S.C. § 103 as obvious over Clinical Trials, Lankford, Hack, '244 publication, Hardeland, Badyal, and Lynch.

68. Whether claim 14 of the '829 patent is invalid under 35 U.S.C. § 103 as obvious over '244 publication, Hardeland, Hack, Rajaratnam, Badyal, and Lynch.

69. Whether Plaintiff has shown that secondary considerations of nonobviousness support a non-obviousness finding and have a nexus to claim 14 of the '829 patent.

VIII. INVALIDITY OF THE '487 PATENT

70. The qualifications and knowledge of a person of ordinary skill in the art pertinent to claims 1 and 5 of U.S. Patent No. 10,376,487 as of the priority date.

71. The scope and content of the prior art and differences (if any) between the claimed inventions of the '487 patent and the prior art.

72. Whether claims 1 and 5 of the '487 patent are invalid under 35 U.S.C. § 103 as obvious.

73. Whether claims 1 and 5 of the '487 patent are invalid under 35 U.S.C. § 103 as obvious over Clinical Trials, Lankford, Hack, and '244 publication.

74. Whether claims 1 and 5 of the '487 patent are invalid under 35 U.S.C. § 103 as obvious over '244 publication, Hardeland, Hack, and Rajaratnam.

75. Whether Plaintiff has shown that secondary considerations of nonobviousness support a non-obviousness finding and have a nexus to claims 1 and 5 of the '487 patent.

76. Whether claims 1 and 5 of the '487 patent are invalid under 35 U.S.C. § 102 as anticipated.

77. Whether claims 1 and 5 of the '487 patent are invalid under 35 U.S.C. § 102 as anticipated by Clinical Trials.

78. Whether claims 1 and 5 of the '487 patent are invalid under 35 U.S.C. § 102 as anticipated by Lankford.

79. Whether claim 1 of the '487 patent is invalid under 35 U.S.C. § 102 as anticipated by '244 Publication.

80. Whether claim 1 of the '487 patent is invalid under 35 U.S.C. § 102 as anticipated by Hardeland.

81. Whether claim 1 of the '487 patent is invalid under 35 U.S.C. § 112 for lack of written description support.

82. Whether claim 1 of the '487 patent is invalid under 35 U.S.C. § 112 as not enabled.

IX. INVALIDITY OF THE '511 PATENT

83. The qualifications and knowledge of a person of ordinary skill in the art pertinent to claims 1 and 5 of U.S. Patent No. 10,610,511 as of the priority date.

84. The scope and content of the prior art and differences (if any) between the claimed inventions of the '511 patent and the prior art.

85. Whether claims 1 and 5 of the '511 patent are invalid under 35 U.S.C. § 103 as obvious.

86. Whether claims 1 and 5 of the '511 patent are invalid under 35 U.S.C. § 103 as obvious over Clinical Trials, Lankford, Hack, and '244 publication.

87. Whether claims 1 and 5 of the '511 patent are invalid under 35 U.S.C. § 103 as obvious over '244 publication, Hardeland, Hack, and Rajaratnam.

88. Whether Plaintiff has shown that secondary considerations of nonobviousness support a non-obviousness finding and have a nexus to claims 1 and 5 of the '511 patent.

89. Whether claims 1 and 5 of the '511 patent are invalid under 35 U.S.C. § 102 as anticipated.

90. Whether claims 1 and 5 of the '511 patent are invalid under 35 U.S.C. § 102 as anticipated by Clinical Trials.

91. Whether claims 1 and 5 of the '511 patent are invalid under 35 U.S.C. § 102 as anticipated by Lankford.

92. Whether claims 1 and 5 of the '511 patent are invalid under 35 U.S.C. § 102 as anticipated by '244 Publication.

93. Whether claims 1 and 5 of the '511 patent are invalid under 35 U.S.C. § 102 as anticipated by Hardeland.

94. Whether claim 1 of the '511 patent is invalid under 35 U.S.C. § 112 for lack of written description support.

95. Whether claim 1 of the '511 patent is invalid under 35 U.S.C. § 112 as not enabled.

X. EXCEPTIONAL CASE

96. Whether this is an exceptional case and Defendants are entitled to an award of attorneys' fees and costs under 35 U.S.C. § 285, and if so, what amount.

97. Whether Defendants are entitled to other just and proper relief and, if so, the appropriate award.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

VANDA PHARMACEUTICALS INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA,
INC., et al.,

Defendants.

C.A. No. 18-651-CFC
(Consolidated)

Exhibit 4 – Plaintiff’s Statement of Contested Issues of Law

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I. LEGAL STANDARDS RELATED TO ISSUES ON WHICH PLAINTIFF BEARS THE BURDEN OF PROOF

A. Infringement, Generally

1. Vanda has the burden of proving infringement by a preponderance of the evidence. *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1366 (Fed. Cir. 2003).

2. “A patentee may prove infringement by any method of analysis that is probative of the fact of infringement, and circumstantial evidence may be sufficient.” *Martek BioSciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1372 (Fed. Cir. 2009) (internal citations and quotations omitted); *see Liquid Dynamics Corp. v. Vaughan Co. Inc.*, 449 F.3d 1209, 1219 (Fed. Cir. 2006).

B. Infringement under 35 U.S.C. § 271(e)(2)

3. In a Hatch-Waxman case, the infringement inquiry under 35 U.S.C. § 271(e)(2) is a hypothetical analysis because it is conducted prior to any actual marketing, sale, or use of the Defendants’ abbreviated new drug application (“ANDA”) products. *Abbott Lab’ys v. Torpharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002) (rehearing denied); *Warner-Lambert*, 316 F.3d at 1365 (the infringement inquiries “are hypothetical because the allegedly infringing product has not yet been marketed.”); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562 at 1570 (Fed. Cir. 1997) (“The relevant inquiry is whether the patentee has proven by a preponderance of the evidence that the alleged infringer will likely market an infringing product.”).

4. Thus, to prove infringement under 35 U.S.C. § 271(e)(2), the patentee needs to show only that it is more likely than not that the proposed ANDA product would, if commercially marketed, satisfy the claim limitations of at least one of the claims of the patents-in-suit. *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 616 F.3d 1283, 1287 (Fed. Cir. 2010); *Abbott Lab 'ys*, 300 F.3d at 1373. Thus, in a Hatch-Waxman suit, “the substantive determination [of] whether actual infringement or inducement will take place is determined by traditional patent infringement analysis, just the same as it is in other infringement suits, including those in a non-ANDA context, the only difference being that the inquiries now are hypothetical because the allegedly infringing product has not yet been marketed.” *Warner-Lambert*, 316 F.3d at 1365. A claim for infringement under Section 271(e)(2) thus encompasses the forms of infringement under other subsections of Section 271.

5. In determining whether a proposed ANDA product would more likely than not infringe at least one claim of at least one of the patents-in-suit, a court must consider all relevant evidence, including the ANDA filing itself. *Abbott Lab 'ys*, 300 F.3d at 1373.

C. Induced Infringement

6. Section 271(b) of Title 35 of the United States Code provides that “[w]hoever actively induces infringement of a patent shall be liable as an infringer.”

7. With regard to patents claiming new methods of treatment, a generic drug ANDA applicant may be liable for inducing infringement, including under 35 U.S.C. § 271(e)(2), even though the generic drug ANDA applicant does not directly infringe a method patent. 35 U.S.C. § 271(b).¹

8. Direct infringement is a necessary predicate for a finding of induced infringement in ordinary patent infringement cases. *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2117, 189 L. Ed. 2d 52 (2014). However, in Hatch-Waxman cases, direct infringement is established “by showing that if the proposed ANDA product were marketed, it would infringe.” *Vanda Pharms. Inc. v. W.-Ward Pharms. Int’l Ltd.*, 887 F.3d 1117, 1130 (Fed. Cir. 2018). Further, in the Hatch-Waxman context, proof of direct infringement does not require proof of past instances of direct infringement by a physician or prescriber. *See Vanda*, 887 F.3d at 1130 (“[P]atentees in Hatch-Waxman litigations asserting method patents do not have to prove that prior use of the NDA-approved drug satisfies the limitations of the asserted claims.”); *see also id.* at 1129 (“As we have explained, ‘section 271(e)(2)(A) makes it possible for a patent owner to have the court determine

¹ Defendants will induce infringement of the following claims: claim 3 of U.S. Patent No. RE46,604 (the RE604 patent); claim 4 of U.S. Patent No. 9,539,234 (the ’234 patent); claim 14 of U.S. Patent No. 10,149,829 (the ’829 patent); claim 4 of U.S. Patent No. 9,730,910 (the ’910 patent); claim 5 of U.S. Patent No. 10,376,487 (the ’487 patent).

whether, if a particular drug *were* put on the market, it *would* infringe the relevant patent.” (quoting *Bristol-Myers Squibb Co. v. Royce Lab’ys, Inc.*, 69 F.3d 1130, 1135 (Fed. Cir. 1995)); *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1368 (Fed. Cir. 2017) (explaining “we have not required evidence regarding the general prevalence of the induced activity”); *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1057 (Fed. Cir. 2010) (affirming district court’s grant of a preliminary injunction based on claims of induced infringement where the district court found that “the proposed label would cause some users to infringe the asserted method claims”); *see also Warner-Lambert*, 316 F.3d at 1364 (“The infringement case is therefore limited to an analysis of whether what the generic drug maker is requesting authorization for in the ANDA would be an act of infringement if performed.”).

9. Circumstantial evidence can support a finding of specific intent to induce infringement. *GlaxoSmithKline LLC v. Teva Pharms. USA, Inc.*, 7 F.4th 1320, 1327 (Fed. Cir. 2021); *AstraZeneca*, 633 F.3d at 1060 (citing *Water Techs. Corp. v. Calco, Ltd.*, 850 F.2d 660, 668 (Fed. Cir. 1988)).

10. “Inducement can be found where there is ‘evidence of active steps taken to encourage direct infringement,’ which can in turn be found in ‘advertising an infringing use or instructing how to engage in an infringing use.’” *Vanda*, 887 F.3d at 1129 (citation omitted) (quoting *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936 (2005)).

11. Thus, where a generic drug maker’s proposed drug label (also known as a “package insert” or “prescribing information”) encourages, recommends, promotes, suggests, instructs, teaches, or requires acts that themselves constitute direct infringement of an asserted patent, the generic drug maker shall be deemed to possess the requisite specific intent to induce infringement and be liable for induced infringement under 35 U.S.C. § 271(b). *Vanda*, 887 F.3d at 1129; *Takeda Pharms. U.S.A., Inc. v. W.-Ward Pharm. Corp.*, 785 F.3d 625, 631 (Fed. Cir. 2015); *AstraZeneca*, 633 F.3d at 1060; *Eli Lilly*, 845 F.3d at 1368. Other evidence, such as advertisements, marketing materials, or other acts, efforts, or materials may also support a generic drug company’s specific intent to induce infringement. *See GlaxoSmithKline*, 7 F.4th at 1337–38.

12. “Even where a proposed label does not explicitly track the language of a claimed method, a package insert containing directives that will ‘inevitably lead some consumers to practice the claimed method’ provides sufficient evidence for a finding of specific intent.” *Sanofi v. Glenmark Pharms. Inc., USA*, 204 F. Supp. 3d 665, 673–74 (D. Del. 2016), *aff’d sub nom. Sanofi v. Watson Lab’ys Inc.*, 875 F.3d 636 (Fed. Cir. 2017) (quoting *AstraZeneca*, 633 F.3d at 1060); *see also Forest Lab’ys Holdings Ltd. v. Mylan Inc.*, 206 F. Supp. 3d 957, 975 (D. Del. 2016).

13. Likewise, a generic drug maker may possess the requisite specific intent, and be liable for induced infringement, even if the generic drug maker’s label

also permits noninfringing uses of the generic drug product. *See Vanda*, 887 F.3d at 1133 (“[E]ven if the proposed ANDA product has ‘substantial noninfringing uses,’ [the generic ANDA applicant] may still be held liable for induced infringement.”); *Sanofi v. Watson Lab’ys Inc.*, 875 F.3d 636, 646 (Fed. Cir. 2017) (“Section 271(b), on inducement, does not contain the ‘substantial noninfringing use’ restriction of section 271(c), on contributory infringement. . . . [A] person can be liable for inducing an infringing use of a product even if the product has substantial noninfringing uses” (citing *Grokster*, 545 U.S. at 934–37)). Thus, so long as the generic drug maker’s proposed drug label encourages, recommends, promotes, suggests, instructs, teaches, or requires that the claimed method of the asserted patents be performed for some patients, the proposed drug label evidences the generic drug maker’s active steps and specific intent to induce infringement. *AstraZeneca*, 633 F.3d at 1049, 1060; *Vanda*, 887 F.3d at 1129; *Eli Lilly*, 845 F.3d at 1368.

14. It is similarly irrelevant to the induced infringement inquiry in a Hatch-Waxman case whether users of the accused ANDA product will allegedly ignore or disregard the language of the drug label. *See AstraZeneca*, 633 F.3d at 1060 (“In the context of specific intent, it is irrelevant that some users may ignore the warnings in the proposed label. The pertinent question is whether the proposed label instructs users to perform the patented method.”).

D. Contributory Infringement

15. Section 271(c) of Title 35 of the United States Code provides that “[w]hoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.”

16. A party is liable for contributory infringement if that party (1) sells, or offers to sell, a material or apparatus for use in practicing a patented process; (2) that material or apparatus is a material part of the invention and must not be a staple article or commodity of commerce that has no substantial noninfringing uses; and (3) the material or apparatus is known by the accused infringer to be especially made or especially adapted for use in an infringement of such patent. *i4i Ltd. P’ship v. Microsoft Corp.*, 598 F.3d 831, 850–51 (Fed. Cir. 2010), *aff’d*, 564 U.S. 91, 131 S. Ct. 2238 (2011); *see also Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1326 (Fed. Cir. 2010); *Lundbeck v. Lupin Ltd.*, No. CV 18-88-LPS, 2021 WL 4944963, at *107 (D. Del. Sept. 30, 2021).

17. With regard to patents claiming new methods of treatment, a generic drug ANDA applicant may be liable for contributing to infringement, including under 35 U.S.C. § 271(e)(2), even though the generic drug ANDA applicant does not directly infringe a method patent. 35 U.S.C. § 271(c).²

18. Direct infringement is a necessary predicate for a finding of contributory infringement in ordinary patent infringement cases. *See, e.g., Cross Med. Prod., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1312 (indicating that a showing of contributory infringement requires “proving an act of direct infringement”) (Fed. Cir. 2005). However, in Hatch-Waxman cases, direct infringement is established “by showing that if the proposed ANDA product were marketed, it would infringe.” *Vanda*, 887 F.3d at 1130. Further, in the Hatch-Waxman context, proof of direct infringement does not require proof of past instances of direct infringement by a physician or prescriber. *Id.* (“[P]atentees in Hatch-Waxman litigations asserting method patents do not have to prove that prior use of the NDA-approved drug satisfies the limitations of the asserted claims.”); *see also id.* at 1129 (“As we have explained, ‘section 271(e)(2)(A) makes it possible for a patent owner to have the court determine whether, if a particular drug *were* put on

² Defendants will contribute to the infringement of the following claims: claim 3 of the RE604 patent; claim 4 of the '234 patent; claim 14 of the '829 patent; claim 4 of the '910 patent; claim 5 of the '487 patent.

the market, it *would* infringe the relevant patent.” (quoting *Bristol-Myers Squibb Co.*, 69 F.3d at 1135)); *Warner-Lambert*, 316 F.3d at 1364 (“The infringement case is therefore limited to an analysis of whether what the generic drug maker is requesting authorization for in the ANDA would be an act of infringement if performed.”).

19. “[N]on-infringing uses are substantial when they are not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental.” *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1327 (Fed. Cir. 2009). The burden of showing the absence of a substantial noninfringing use is on the party asserting patent infringement. *See Golden Blount, Inc. v. Robert H. Peterson Co.*, 438 F.3d 1354, 1363 (Fed. Cir. 2006). However, “[o]nce a patentee has made out a *prima facie* showing that a product is not ‘suitable for substantial non-infringing use,’ the burden then shifts to the accused infringer to demonstrate otherwise.” *In re Depomed Patent Litig.*, No. 13-4507 (CCC-MF), 2016 WL 7163647, at *25 (D.N.J. Sept. 30, 2016) (quoting *Golden Blount*, 438 F.3d at 1363).

20. The off-label use of a drug is not a substantial noninfringing use sufficient to defeat a finding of contributory infringement for “a product that is authorized to be sold solely for the infringing use.” *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 435 F. App’x 917, 927 (Fed. Cir. 2011).

E. Infringement of the Product-by-Process Claim under 35 U.S.C. § 271(e)(2) Based on 35 U.S.C. § 271(a)

21. Claim 10 of U.S. Patent No. 10,829,465 (the '465 patent) claims products made by a specified process, commonly known as a “product-by-process claim.” A generic drug ANDA applicant may be liable for infringement of a product-by-process claim, including under 35 U.S.C. § 271(e)(2), based on 35 U.S.C. § 271(a). Defendants have or will directly infringe claim 10 of the '465 patent under 35 U.S.C. § 271(e)(2) based on 35 U.S.C. § 271(a).

22. “Each element contained in a patent claim is deemed material to defining the scope of the patented invention.” *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997). “[P]rocess terms in product-by-process claims serve as limitations in determining infringement.” *Abbott Lab’ys v. Sandoz, Inc.*, 566 F.3d 1282, 1293 (Fed. Cir. 2009) (citation omitted).

23. A product accused of infringing a product-by-process claim that was made by a process outside the United States will not defeat a claim of infringement under 35 U.S.C. § 271(a). *See McAirlaids, Inc. v. Kimberly-Clark Corp.*, No. 7:13cv193, 2013 WL 6882699, at *2 (W.D. Va. Dec. 31, 2013) (“Nothing in the clear language of § 271(a) requires the process steps of a product-by-process claim to occur in the United States as an element of infringement. Nor has any case so held.”); *see also Gemtron Corp. v. Saint-Gobain Corp.*, 572 F.3d 1371, 1380 (Fed. Cir. 2009).

F. Infringement of the Product-by-Process Claim under 35 U.S.C. § 271(e)(2) Based on 35 U.S.C. § 271(g)

24. With regard to patents claiming new products-by process, a generic drug ANDA applicant may also be liable for infringement, including under 35 U.S.C. § 271(e)(2), based on 35 U.S.C. § 271(g). Defendants have or will directly infringe claim 10 of the '465 patent under 35 U.S.C. § 271(e)(2) based on 35 U.S.C. § 271(g). Claim 10 of the '465 patent is a product-by-process claim.

25. Under 35 U.S.C. § 271(g), “[w]hoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent.” Further, “[a] product which is made by a patented process will, for purposes of this title, not be considered to be so made after—(1) it is materially changed by subsequent processes; or (2) it becomes a trivial and nonessential component of another product.” *Id.*

26. Congress enacted Section 271(g) to deter entities from using a process patented in the United States abroad and then importing into the United States a product made by the process. “[T]he focus [of liability under Section 271(g)] is only on acts with respect to products resulting from the patented process.” *Syngenta Crop Protection, LLC v. Willowood, LLC*, 944 F.3d 1344, 1359–60 (Fed. Cir. 2019).

27. Liability under Section 271(g) does not turn on whether Defendants themselves manufacture the accused product or whether the accused product is made by a single entity or multiple entities. *See Syngenta*, 944 F.3d at 1359 (“We conclude that the district court erred by imposing a single-entity requirement under § 271(g)”); *id.* at 1360 (“[W]hether th[e] [claimed] process is practiced by a single entity is immaterial to the infringement analysis under that section.”). Rather, “the acts that give rise to liability under § 271(g) are the importation, offer for sale, sale, or use within this country of a product that was made by a process patented in the United States.” *Id.* at 1359.

28. Whether the accused product is materially changed by subsequent processes or becomes a trivial and nonessential component of another product under 35 U.S.C. § 271(g)(1)-(2) are defenses to a Section 271(g) infringement claim and are therefore the accused infringer’s burden to prove. *Kinik Co. v. Int’l Trade Comm’n*, 362 F.3d 1359, 1361–62 (Fed. Cir. 2004) (referring to 271(g)(1) and 271(g)(2) as defenses); *Kyowa Hakka Bio, Co. v. Ajinomoto Co.*, No. CV 17-313, 2018 WL 834583, at *9 (D. Del. Feb. 12, 2018) (“The limits on liability set forth in § 271(g)(1) and (2) have been characterized by the Federal Circuit as ‘defenses’ or ‘exceptions’ not as elements of a § 271(g) claim that must be affirmatively pled.” (citing *Kinik*, 362 F.3d at 1362)).

29. Nevertheless, in the case of an active pharmaceutical ingredient (“API”) product made by a product-by-process claim, such product is not “materially changed by subsequent processes” simply because the subsequent processes change the “shape, size, or form” of the API or combine the API with excipients to make a drug product (e.g., a capsule). H.R. REP. NO. 60, 100th Cong., 1st. Sess. 13–14 (1987) (“Processing steps which only change shape, size or form are also not material. For example, if chemical X were a polyester resin, the use, sale, or importation of the resin could constitute an act of infringement regardless of whether the resin was formed into yarn or fabricated into some other physical object. Similarly, if chemical X was the active ingredient of a pharmaceutical product, or one of its active ingredients, liability for infringement is not avoided by putting chemical X in a tablet or some other dosage form.”).

30. Likewise, for a drug product with a single API, the API made by a patented process is not a “trivial or nonessential component” of the drug product for which a generic drug maker has sought FDA approval to market, sell, and/or distribute pursuant to an ANDA.

II. ISSUES ON WHICH PLAINTIFF BEARS THE BURDEN OF PROOF

A. Infringement of the Method-of-Treatment Patent Claims

31. Defendants have infringed, pursuant to 35 U.S.C. § 271(e)(2)(A), and, pursuant to 35 U.S.C. § 271(b), will induce infringement of, claim 3 of the RE604

patent; claim 4 of the '234 patent; claim 14 of the '829 patent; claim 4 of the '910 patent; and claim 5 of the '487 patent by seeking FDA approval to make, use, sell, offer for sale, distribute, market, and/or otherwise commercialize a generic tasimelteon (20 mg capsules) product that contains a drug label (also known as a “package insert” or “prescribing information”) that instructs, teaches, encourages, recommends, requires, suggests, and/or promotes the use and/or administration of their generic tasimelteon products in a manner that practices these claims.

32. Defendants have infringed, pursuant to 35 U.S.C. § 271(e)(2)(A), and, pursuant to 35 U.S.C. § 271(c), will contribute to infringement of claim 3 of the RE604 patent; claim 4 of the '234 patent; claim 14 of the '829 patent; claim 4 of the '910 patent; and claim 5 of the '487 patent by seeking FDA approval to make, use, sell, offer for sale, distribute, market, and/or otherwise commercialize a generic tasimelteon (20 mg capsules) product that contains a drug label (also known as a “package insert” or “prescribing information”), which Defendants know are especially made for a use that infringes these patents and constitute, separately and together, a material part of the claimed inventions, and are not a staple commodity or article suitable for a substantial noninfringing use.

B. Infringement of the '465 Patent

33. Defendants have infringed, pursuant to 35 U.S.C. § 271(e)(2)(A), and, upon FDA approval of their ANDA products will infringe, pursuant to 35 U.S.C.

§ 271(a), claim 10 of the '465 patent, by making, using, selling, and/or offering for sale within the United States, and/or importing into the United States their generic tasimelteon drug products, which are made in a manner that practices these claims.

34. Defendants have infringed, pursuant to 35 U.S.C. § 271(e)(2)(A), and, upon FDA approval of their ANDA products will infringe, pursuant to 35 U.S.C. § 271(g), claim 10 of the '465 patent, by importing into the United States, offering to sell, selling, or using within the United States, their generic tasimelteon products which are made by a process that practices these claims.

III. RELIEF

A. Relief under 35 U.S.C. § 271(e)(4)

35. Under 35 U.S.C. § 271(e)(2)(A), it is an act of infringement to submit an ANDA “for a drug claimed in a patent or the use of which is claimed in a patent.” 35 U.S.C. § 271(e)(2)(A). Sections 271(e)(4)(A) and (B) specify that the remedy for such infringement is that “(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,” 35 U.S.C. § 271(e)(4)(A), and “(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product,” 35 U.S.C. § 271(e)(4)(B).

B. Exceptional Case

36. “The court in exceptional cases may award reasonable attorney fees to the prevailing party.” 35 U.S.C. § 285.

37. “[A]n ‘exceptional’ case is simply one that stands out from others with respect to the substantive strength of a party’s litigating position . . . or the unreasonable manner in which the case was litigated.” *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 554 (2014). There is “no precise rule or formula” for awarding attorneys’ fees under § 285. *Id.* District courts should “consider[] the totality of the circumstances.” *Id.* A district court’s “discretion should be exercised ‘in light of the considerations’” underlying the grant of that discretion. *Id.*

IV. LEGAL STANDARDS RELATED TO ISSUES ON WHICH DEFENDANTS BEAR THE BURDEN OF PROOF

A. Invalidity, Generally

38. By statute, patents are “presumed valid.” 35 U.S.C. § 282(a). A party challenging the validity of a patent therefore bears a “high burden” of proof by clear and convincing evidence. *Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1260 (Fed. Cir. 2012).

39. This presumption of validity applies to each patent claim individually and with respect to all challenges to the validity of a patent on any grounds. *See Cont’l Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1266–67 (Fed. Cir. 1991)

(“Each claim carries an independent presumption of validity, 35 U.S.C. § 282, and stands or falls independent of the other claims.”); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1375 (Fed. Cir. 1986) (“[T]he presumption of validity goes to validity of the patent in relation to the patent statute *as a whole*; not just to nonobviousness under section 103.”).

40. Because a patent is presumed valid, the patent holder bears no burden or obligation to prove that the asserted patent claims are valid—the burden of persuasion always lies with the patent challenger. *See Commil USA, LLC v. Cisco Sys., Inc.*, 575 U.S. 632, 643 (2015) (“Under the Patent Act, and the case law before its passage, a patent is presumed valid. That presumption takes away any need for a plaintiff to prove his patent is valid to bring a claim.” (citations omitted)); *Bates v. Coe*, 98 U.S. 31, 40 (1878) (“Power to grant patents is conferred upon the commissioner; and when that power has been duly exercised, it is of itself, when introduced in evidence in cases like the present, prima facie evidence that the patentee is the original and first inventor of that which is therein described as his invention. Proof may be introduced by the respondent to overcome that presumption; but in the absence of such proof, the prima facie presumption is sufficient to enable the party instituting the suit to recover for the alleged violation of his rights.”).

41. Under the clear and convincing evidence standard, a party alleging invalidity must create “in the mind of the trier of fact an abiding conviction that the

truth of a factual contention is highly probable.” *Price v. Symsek*, 988 F.2d 1187, 1191 (Fed. Cir. 1993) (quotations omitted).

42. A party alleging that a patent claim is obvious or anticipated based on references that were before the U.S. Patent and Trademark Office (“PTO”) when the patent application was under review has “the added burden of overcoming the deference that is due to a qualified government agency presumed to have properly done its job, which includes one or more examiners who are assumed to have some expertise in interpreting the references and to be familiar from their work with the level of skill in the art and whose duty it is to issue only valid patents.” *Shire LLC v. Amneal Pharms., LLC*, 802 F.3d 1301, 1307 (Fed. Cir. 2015) (quoting *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1304 (Fed. Cir. 2008); *see also Glaxo Grp. Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1348 (Fed. Cir. 2004) (proving obviousness “‘especially difficult’ when, as is the present case, the infringer attempts to rely on prior art that was before the patent examiner during prosecution”) (quoting *Al-Site Corp. v. VSI Int’l Inc.*, 174 F.3d 1370, 1377 (Fed. Cir. 1999); *Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 109 (2011) (“[B]ecause the heightened standard of proof applied where the evidence before the court was ‘different’ from that considered by the PTO, it applied even more clearly where the evidence was identical.” (quoting *RCA v. Radio Eng’g Lab’ys*, 293 U.S. 1, 8 (1934))). Relatedly, the burden is on the patent challenger to prove that the asserted prior art was not considered by the PTO.

See Lindemann Maschinenfabrik GMBH v. Am. Hoist and Derrick Co., 730 F.2d 1452, 1460 (Fed. Cir. 1984) (“To the extent that the examiner’s consideration of uncited art is material, the burden is on the challenger to show that ‘that prior art had *not* been considered.’”) (emphasis in original).

43. An asserted reference does not qualify as a prior art printed publication under pre-AIA 35 U.S.C. § 102(a), (b) and AIA 35 U.S.C. § 102(a)(1) until the date it reaches the public. “Public accessibility requires more than technical accessibility.” *Acceleration Bay, LLC v. Activision Blizzard Inc.*, 908 F.3d 765, 773 (Fed. Cir. 2018). “In order to qualify as a printed publication within the meaning of § 102, a reference must have been sufficiently accessible to the public interested in the art. Because there are many ways in which a reference may be disseminated to the interested public, ‘public accessibility’ has been called the touchstone in determining whether a reference constitutes a ‘printed publication’ bar under 35 U.S.C. § 102(b). Whether a reference is publicly accessible is determined on a case-by-case basis based on the facts and circumstances surrounding the reference’s disclosure to members of the public. A reference is considered publicly accessible if it was disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, can locate it.” *In re Lister*, 583 F.3d 1307, 1311 (Fed. Cir. 2009) (internal quotations and citations omitted).

44. The patent challenger bears the burden of proving by clear and convincing evidence that “prior to the critical date the reference was sufficiently accessible, at least to the public interested in the art, so that such a one by examining the reference could make the claimed invention without further research or experimentation.” *In re Hall*, 781 F.2d 897, 899 (Fed. Cir. 1986).

B. Person of Ordinary Skill

45. “Factors that may be considered in determining level of ordinary skill in the art include: (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field.” *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007). However, “[t]hese factors are not exhaustive but are merely a guide to determining the level of ordinary skill in the art.” *Id.*; *see also Alcon, Inc. v. Teva Pharms. USA, Inc.*, 664 F. Supp. 2d 443, 454 (D. Del. 2009) (“Courts use these factors as a guide, and the weight or significance the court ascribes to these or similar factors will depend on the case.” (citing *Env’t Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696 (Fed.Cir.1983))).

C. Anticipation

46. “Claimed subject matter is ‘anticipated’ when it is not new; that is, when it was previously known. Invalidation on this ground requires that every

element and limitation of the claim was previously described in a single prior art reference, either expressly or inherently, so as to place a person of ordinary skill in possession of the invention.” *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1082 (Fed. Cir. 2008).

47. A claimed invention is not anticipated, however, by the experimental work of the inventors or those under the direction and control of the inventors, such as clinical trials performed by or on behalf of the inventors. *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1381 (Fed. Cir. 2006) (finding the “experimental character” of clinical trials “negated any statutory bar.”); *see also City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126, 137 (1877) (“[I]t is the interest of the public, as well as himself, that the invention should be perfect and properly tested, before a patent is granted for it.”); *Paeco, Inc. v. Applied Moldings, Inc.*, 562 F.2d 870, 872 (3d Cir. 1977) (“Once the party asserting invalidity has convincingly proven the prior use or sale, however, the burden shifts to the patentee to prove that any prior use, sale, or printed publication was for experimental, not commercial, purposes.”). This doctrine of experimental use not qualifying as an invalidating public use or on-sale bar under 35 U.S.C. § 102(b) traces its origins to the U.S. Supreme Court’s decision in *City of Elizabeth*. There, the Court held that the construction of a prototype pavement material on a strip of public road was not a “public use” precluding patentability because “the nature of a street pavement is

such that it cannot be experimented upon satisfactorily except on a highway, which is always public” and “it is the interest of the public, as well as himself, that the invention should be perfect and properly tested, before a patent is granted for it.” *City of Elizabeth*, 97 U.S. at 134, 137.

48. Likewise, the law compels the public disclosure of certain experiments; namely, clinical trials that are designed to determine whether the use of a potentially therapeutic drug used to treat a particular disease under specific parameters is patentable. Those clinical trials must be posted to the publicly available website clinicaltrials.gov when they are (1) controlled clinical investigations, other than Phase I clinical investigations, are subject to either Section 505 of the Food, Drug, and Cosmetic Act, or Section 351 of the Public Health Service Act, and the studied product is approved, licensed, or cleared by FDA (or the primary completion date of the trial is on or after January 18, 2017). 42 CFR §§ 11.10(a), 11.42. Therefore, such experimental work, which would not be anticipatory if asserted as an invalidating public use or on-sale bar, cannot be deemed anticipatory if its disclosure by the patent inventors is compelled by law.

1. Anticipatory Reference Must Be Enabling

49. An asserted reference is anticipatory only when it is enabling; “that is, the description must be such that a person of ordinary skill in the field of the invention can practice the subject matter based on the reference, without undue

experimentation.” *Sanofi-Synthelabo*, 550 F.3d at 1082. As with the assessment of enablement of an asserted patent under 35 U.S.C. § 112, the factors set forth in *Wands* are relevant to determining whether an allegedly anticipatory reference is enabled without undue experimentation. *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988); *Sanofi-Synthelabo*, 550 F.3d at 1085. The *Wands* factors include “(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.” *Wands*, 858 F.2d at 737.

50. Thus, in order to anticipate, the asserted reference “must sufficiently describe the claimed invention to have placed the public in possession of it.” *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985); *see also id.* (“[E]ven if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling.”).

51. For prior art other than issued patents, the law is unsettled as to whether the patent challenger bears the burden of proving that it is enabling or whether the patentee bears the burden of proving the opposite. *See Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355 n.22 (Fed. Cir. 2003).

2. Inherent Disclosure

52. In order for a claim element to be inherently disclosed by an asserted prior art reference, it must be necessarily and inevitably present in that disclosure. *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 961 (Fed. Cir. 2014) (affirming judgment that claims were not inherently anticipated where the prior art only showed that the limitation might occur, not that it inevitably occurred); *See also in re Armodafinil Patent Litig. Inc.*, 939 F. Supp. 2d 456, 469–70 (D. Del. 2013). Inherency “may not be established by probabilities or possibilities.” *Bettcher Indus., Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 639 (Fed. Cir. 2011); *see also Galderma Lab’ys, L.P. v. Teva Pharms. USA, Inc.*, 799 F. App’x 838, 845 (Fed. Cir. 2020) (reversing district court ruling that efficacy limitation is inherent in asserted reference, stating that the proper inquiry was whether the efficacy limitation “necessarily result from practicing” the asserted reference); *Rapoport v. Dement*, 254 F.3d 1053, 1062–63 (Fed. Cir. 2001) (finding “speculative” an inherent anticipation argument based on the “assumption[] that a treatment regimen of three doses a day would necessarily include an administration ‘at the time of sleep’”).

3. On-Sale Bar

53. Under the American Invents Act (“AIA”), “a person shall be entitled to a patent unless the claimed invention was . . . on sale . . . before the effective filing date of the claimed invention.” 35 U.S.C.A. § 102(a)(1). The patent statute,

however, permits a one-year grace period after the invention on sale before the entitlement to a patent is barred. 35 U.S.C.A. § 102(b). “The statute guards against undue delay in commencing the patenting process, while providing a year wherein an inventor may assess the commercial potential of the invention without losing the opportunity of patenting it in the United States.” *Gemmy Indus. Corp. v. Chrisha Creations Ltd.*, 452 F.3d 1353, 1358 (Fed. Cir. 2006).

54. A product is “on sale” if it satisfies the two-part test set forth in *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55 (1998); namely, whether the claimed invention was (1) the subject of a commercial offer for sale; and (2) ready for patenting at the time of that offer for sale. *See Meds. Co. v. Hospira, Inc.*, 827 F.3d 1363, 1368 (Fed. Cir. 2016) (en banc) (citing *Pfaff*, 525 U.S. at 67–68); *see also Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 139 S. Ct. 628, 630 (“[T]he reenactment of the phrase ‘on sale’ in the AIA did not alter this meaning.”).

55. The patent challenger bears the burden of proof by clear and convincing evidence as to whether a product was “on sale” under *Pfaff*’s two-part test. *Gemmy*, 452 F.3d at 1358; *Emergency Fuel, LLC v. Penzoil-Quaker State Co.*, 71 F. App’x 826, 834 (Fed. Cir. 2003).

56. Whether the on-sale bar applies is a question of law, under Federal Circuit law, based on underlying factual findings about whether the two *Pfaff* factors are satisfied. *Meds. Co.*, 827 F.3d at 1371, 1373 (quoting *Grp. One, Ltd. v. Hallmark*

Cards, Inc., 254 F.3d 1041, 1047 (Fed. Cir. 2001)). The law applied to the question of whether the invention is the subject of a commercial offer for sale is analyzed under the law of contracts as generally understood. *Id.* at 1371. The Federal Circuit has stated that the on-sale bar inquiry focuses on those activities that would be understood to be commercial sales and offers for sale “in the commercial community.” *Id.* at 1373.

57. To determine whether a product was the subject of a commercial sale, as a general matter, the Federal Circuit will look to the Uniform Commercial Code (“UCC”) to define whether a communication or series of communications rises to the level of a commercial offer for sale. *Meds. Co.*, 827 F.3d at 1375 (citing *Grp. One, Ltd.*, 254 F.3d at 1047). The UCC describes a “sale” as “the passing of title from the seller to the buyer for a price.” *Id.* (quoting UCC § 2-106(1)). The UCC’s definition of “sale” carries significant weight in the inquiry; however, it is not dispositive. *Id.*

58. To determine whether the communication constituted an offer for sale, the Federal Circuit also looks at the confidential nature of the transaction. *Meds. Co.*, 827 F.3d at 1376. Finding that a transaction and the communications relating thereto were confidential weighs in favor of the court holding that the transaction did not place the invention on sale, but confidentiality is not dispositive. *Id.* (“[T]he

confidential nature of the transactions is a factor which weighs against the conclusion that the transactions were commercial in nature.”).

59. The “mere sale of manufacturing services” does not qualify as a sale for purposes of the on-sale bar, *id.* at 1373, and a contract development and/or manufacturing organization acting as a pair of “laboratory hands” on behalf of the patentee does not trigger the on-sale bar. *Id.* at 1375; *see also Trading Techs. Int’l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1361 (Fed. Cir. 2010) (recognizing that inventors can request assistance from a third party in developing embodiments of the invention without triggering the on-sale bar).

60. Likewise, the absence of transfer of title is indicative of there being no applicable sale. *See Meds. Co.*, at 1376 (“[T]he absence of title transfer [is] significant because, in most instances, that fact indicates an absence of commercial marketing of the product by the inventor.”).

61. The sale or offer to sell must be for the claimed invention and the invention must be ready for patenting at the time of the transaction. *Barry v. Medtronic, Inc.*, 914 F.3d 1310, 1331 (Fed. Cir. 2019); *In re Caveney*, 761 F.2d 671, 675 (Fed. Cir. 1985); *see also Netscape Commc’ns Corp. v. Konrad*, 295 F.3d 1315, 1323 (Fed. Cir. 2002). The on-sale bar requires that there be a sale “of the entire claimed invention.” *Dey, L.P. v. Teva Parenteral Meds., Inc.*, 6 F. Supp. 3d 651, 671 (N.D. W. Va. 2014); *Dana Corp. v. Am. Axle & Mfg., Inc.*, 279 F.3d 1372, 1375

(Fed. Cir. 2002) (“When the asserted basis of invalidity is a public use or on-sale bar, the court should determine ‘whether the subject of the barring activity met each of the limitations of the claim, and thus was an embodiment of the claimed invention.’” (quoting *Scaltech Inc. v. Retec/Tetra, L.L.C.*, 178 F.3d 1378, 1383 (Fed. Cir. 1999))). One way to demonstrate readiness for patenting is by showing a reduction to practice, i.e., that the inventor constructed an embodiment or performed a process that met all the claim limitations and determined that the invention would work for its intended purpose. *Pfaff*, 525 U.S. at 67–68; *Barry*, 914 F.3d at 1328. Defining the intended purpose is a question of law based on the claims and specification of a patent. *See Manning v. Paradis*, 296 F.3d 1098, 1102–04 (Fed. Cir. 2002).

62. Courts have long recognized an experimental use exception to the on-sale bar, which allows patentees to engage in transactions with third parties if such transactions were for purposes of testing their invention. *See, e.g., City of Elizabeth*, 97 U.S. at 135; *Barry*, 914 F.3d at 1328; *see also Helsinn*, 139 S. Ct. at 630 (holding that the on-sale bar under the AIA is the same as the on-sale bar pre-AIA). For example, a transaction, “if made in good faith solely to test the qualities of the invention, and for the purpose of experiment, is not a public use [or sale] within the meaning of the statute.” *Egbert v. Lippmann*, 104 U.S. 333, 336 (1881); *see also Lisle Corp. v. A.J. Mfg. Co.*, 398 F.3d 1306, 1313 (Fed. Cir. 2005). A patentee only

needs to “simply produce sufficient rebuttal evidence to prevent the party challenging the patent’s validity from meeting its burden of proving by clear and convincing evidence” that the invention was on sale. *Id.* at 1316. “Adequate proof of experimental use negates the statutory bar.” *Honeywell Int’l, Inc. v. Universal Avionics Sys. Corp.*, 343 F. Supp. 2d 272, 293 (D. Del. 2004).

63. “To determine whether a use is ‘experimental,’ a question of law, the totality of the circumstances must be considered” *Lough v. Brunswick Corp.*, 86 F.3d 1113, 1120 (Fed. Cir. 1996). A use may be experimental if its purpose is to test the claimed features of the invention or to determine whether an invention will work for its intended purpose. *Pfaff*, 525 U.S. at 64; *Barry*, 914 F.3d at 1328. When a product is only used for “experimental, development purposes[,]” such as “to conduct . . . laboratory research,” the on-sale bar does not apply because the “commercial” sale element of the bar is not met. *In re Bendamustine Consol. Cases*, No. 13-2046, 2016 WL 3381219, at *13 (D. Del. June 10, 2016).

64. Thus, where a transaction has occurred, courts will consider whether the transaction occurred as a means of furthering research or out of an effort to commercialize the process. *See id.* In *Bendamustine*, the patented formulation was provided to a separate entity in multiple batches to conduct phase II clinical trials and laboratory research. *Id.* Because the product was only used for “experimental, development purposes[,]” the court held that the on-sale bar did not apply—the

“commercial” sale element of the bar was not met. *Id.* As another example, in *Boston Sci. Corp. v. Cordis Corp.*, the fact-finder determined that there was no on-sale bar even when the patentee of a system of radiopaque markers provided UCLA with an order of 62 units, charging UCLA \$300 per marker and \$280 per catheter. No. C 02-01474 JW, 2008 WL 11387141, at *4 (N.D. Cal. Jan. 25, 2008). In so determining, the court explained that (1) the nominal fee was used to recoup research and development costs associated with the invention; (2) the specific order was just “one element of a research and development collaboration between” the patentee and UCLA; and (3) the units were used in clinical trials at UCLA. *Id.* at *5. As such, the court concluded that the order “was a sale primarily for experimentation, and not for commercial purposes.” *Id.*

65. Similarly, because the use of a drug formulation in clinical trials is important for determining the utility of the formulation, the manufacture or use of such formulation is unlikely to constitute an invalidating sale or public use. For example, in *In re Omeprazole Patent Litig.*, the court explained that “[w]hen a pharmaceutical company tests a formulation in clinical trials, it does not know whether the trials will be successful or enable it to file an application for FDA approval. Clinical trial testing is uncertain and many drugs and formulations fail, even after successful prior trials. Even after an FDA application is filed, there is no assurance that approval will be granted. Impax’s proposed theory, if accepted,

would unduly force the hand of inventors of new pharmaceutical formulations to file for patents prior to sufficiently testing the safety and efficacy of the formulation. There is simply nothing in the patent law or its underlying policy which requires or supports this.” 490 F. Supp. 2d 381, 509 (S.D.N.Y. 2007). The court in *In re Omeprazole* accordingly held that the clinical trials, without other evidence that the involved parties attempted to commercially exploit the trials, did not constitute a public use or implicate the on-sale bar. *Id.*

D. Obviousness

66. “The determination of obviousness under 35 U.S.C. § 103 is a legal conclusion based on underlying facts.” *Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286, 1290 (Fed. Cir. 2013). A patent claim is invalid for obviousness if “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” 35 U.S.C. § 103.

67. As set forth in *Graham*, obviousness is a question of law based on the following factual findings: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the art; and (4) objective indicia of nonobviousness. 383 U.S. at 17–18. *See Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1360 (Fed. Cir. 2012).

68. “At all times, the burden is on the defendant to establish by clear and convincing evidence that the patent is obvious.” *Id.* at 1360.

69. The patentability of an invention “shall not be negated by the manner in which the invention was made.” 35 U.S.C. § 103; *Honeywell Int’l Inc. v. Mexichem Amanco Holding S.A.*, 865 F.3d 1348, 1356 (Fed. Cir. 2017) (explaining that this provision “was enacted to ensure that routine experimentation does not necessarily preclude patentability”).

70. As part of the court’s obviousness analysis, it must assess an asserted reference “for all it taught, disclosures that diverged and taught away from the invention at hand as well as disclosures that pointed towards and taught the invention at hand.” *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 296 (Fed. Cir. 1985). “Even if a reference is not found to teach away, its statements regarding preferences are relevant to a finding regarding whether a skilled artisan would be motivated to combine that reference with another reference.” *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1069 (Fed. Cir. 2018); *see also In re Hedges*, 783 F.2d 1038, 1041 (Fed. Cir. 1986) (“It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.”)

71. An invention is not obvious over a proposed modification or combination of the prior art that is taught away from, i.e., when a person of ordinary skill, upon examining the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. *Unigene Lab'ys, Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1361 (Fed. Cir. 2011); *see also Crocs, Inc. v. Int'l Trade Comm'n*, 598 F.3d 1294, 1308–09 (Fed. Cir. 2010).

72. The asserted prior art must also enable the claimed invention in order to support an obviousness challenge. *Raytheon Techs. Corp. v. Gen. Elec. Co.*, 993 F.3d 1374, 1380 (Fed. Cir. 2021) (“To render a claim obvious, the prior art, taken as a whole, must enable a skilled artisan to make and use the claimed invention.”).

73. In addition, the references asserted to prove obviousness only qualify as relevant prior art if they are analogous to the claimed invention. *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004). A reference is deemed analogous for purposes if it is either (1) from the “same field of endeavor” as that of the inventors of the challenged patent or (2) “reasonably pertinent to the particular problem with which the inventor [of the challenged patent] is involved.” *Id.* at 1325.

1. Motivation to Combine with Reasonable Expectation of Success

74. As part of the patent challenger’s burden, they must prove by clear and convincing evidence that a POSA would have been motivated to combine the

teachings of the asserted prior art references to achieve the claimed invention and also that such a POSA would have had a reasonable expectation of successfully achieving the claimed invention by that combination. *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009) (“A party seeking to invalidate a patent based on obviousness must demonstrate by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.” (citation omitted)).

75. Motivation to combine and reasonable expectation of success are related, but separate, elements of the patent challenger’s burden on obviousness. *Eli Lilly & Co. v. Teva Pharms. Int’l GmbH*, 8 F.4th 1331, 1344 (Fed. Cir. 2021) (“A finding by the Board that a patent challenger has demonstrated a motivation to combine references does not necessarily imply that the challenger has also met its burden of showing a reasonable expectation of success in achieving a claimed method of treatment.”).

76. Thus, in *Eli Lilly*, the Federal Circuit held that, in seeking to prove obviousness for the asserted method treatment claims, “which are written in a ‘method for treating’ format and comprise a single step of administering an effective amount of a compound, . . . [the patent challenger] must not only prove that a skilled

artisan would be motivated to combine Olesen, Tan, and Queen, but also that the skilled artisan would have reasonably expected success in administering a humanized anti-CGRP antagonist antibody for treating at least one vasomotor symptom.” *Id.* at 1344.

77. Further, “merely asserting that a given modification would have been obvious to a skilled artisan does not make it so.” *Takeda Pharm. Co. Ltd. v. Torrent Pharms. Ltd.*, 844 F. App’x 339, 343 (Fed. Cir. 2021); *TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1359 (Fed. Cir. 2019) (“‘[A] conclusory assertion with no explanation is inadequate to support a finding that there would have been a motivation to combine’ because ‘[t]his type of finding, without more, tracks the ex post reasoning *KSR* warned of and fails to identify any actual reason why a skilled artisan would have combined the elements in the manner claimed.’” (quoting *In re Van Os*, 844 F.3d 1359, 1361–62 (Fed. Cir. 2017))); *Wasica Fin. GmbH v. Cont’l Auto. Sys., Inc.*, 853 F.3d 1272, 1286 (Fed. Cir. 2017) (“As we have stated, obviousness determinations cannot be sustained by merely conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” (citation omitted))

(a) Motivation to Combine

78. The patent challenger must establish by clear and convincing evidence that there existed in the prior art a need or problem that is addressed by the patent

and would have motivated a person of ordinary skill in the art to combine the teachings of the asserted prior art in a manner that reflects the challenged patent claims. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007). “The showing of a motivation to combine must be clear and particular, and it must be supported by actual evidence.” *Teleflex, Inc. v. Ficosa North America Corp.*, 299 F.3d 1313, 1334 (Fed. Cir. 2002).

79. This means that the patent challenger must prove that a POSA would have been *motivated* to combine teachings of the prior art references in a manner that would produce the claimed invention, *not* what a POSA would be *able* to do based on the teachings of the prior art. The latter approach succumbs to hindsight. *See Polaris*, 882 F.3d at 1068 (“[T]he Board focused on what a skilled artisan would have been *able* to do, rather than what a skilled artisan would have been *motivated* to do at the time of the invention.”); *InTouch Techs., Inc. v. VGO Commc’ns, Inc.*, 751 F.3d 1327, 1352 (Fed. Cir. 2014) (concluding that a party’s expert “succumbed to hindsight bias in her obviousness analysis” where such analysis “primarily consisted of conclusory references to her belief that one of ordinary skill in the art could combine these references, not that they would have been motivated to do so”).

80. When a patent challenger contends that a patent is obvious in light of a combination or modification of prior art references, the challenger must point to clear and convincing evidence that shows that there existed a reason to make the

change. *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356–57 (Fed. Cir. 2007); *Yamanouchi Pharm. Co., Ltd. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1344–45 (Fed. Cir. 2000) (affirming that Defendants “did not show sufficient motivation for one of ordinary skill in the art at the time of invention to take any one of the following steps, let alone the entire complex combination”); *Hybritech*, 802 F.2d at 1383 (“Focusing on the obviousness of substitutions and differences instead of on the invention as a whole . . . was a legally improper way to simplify the difficult determination of obviousness.”).

81. “[K]nowledge of a problem and motivation to solve it are entirely different from motivation to combine particular references to reach the particular claimed method.” *Innogenetics, N.V. v. Abbott Lab’ys*, 512 F.3d 1363, 1373 (Fed. Cir. 2008); *see also Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 381 F.3d 1371, 1377 (Fed. Cir. 2004) (“Recognition of a need does not render obvious the achievement that meets that need. . . . Recognition of an unsolved problem does not render the solution obvious.”); *Leo Pharm. Prods., Ltd. v. Rea*, 726 F.3d 1346, 1353–54 (Fed. Cir. 2013) (finding that because the prior art does not disclose the problem discovered, there was no motivation to combine prior art elements to solve that problem); *Novartis Pharm. Corp. v. Watson Lab’ys, Inc.*, 611 F. App’x 988, 995 (Fed. Cir. 2015) (“Even an obvious solution, however, does not render an invention obvious if the problem solved was previously unknown.”); *id.* at 996 (“Although the

addition of an antioxidant would have been an obvious solution for a formulation with known oxidation problems, here Watson failed to prove that a rivastigmine formulation was known to be susceptible to oxidative degradation.”).

82. Where a prior art reference teaches away from its combination with another source, the reference cannot be combined as part of the alleged obviousness theory. *Tec Air, Inc. v. Denso Mfg. Michigan Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999).

(b) Reasonable Expectation of Success

83. The POSA’s alleged reasonable expectation of successfully achieving the claimed invention “must be founded in the prior art,” not in the challenged patent’s disclosure. *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991).

84. In an unpredictable field like drug development, a lack of relevant data in the prior art can weigh heavily in favor of nonobviousness. *OSI Pharms., LLC v. Apotex Inc.*, 939 F.3d 1375, 1385 (Fed. Cir. 2019) (“These references provide no more than hope—and hope that a potentially promising drug will treat a particular cancer is not enough to create a reasonable expectation of success in a highly unpredictable art such as this.”); *Honeywell* 865 F.3d at 1356 (“Unpredictability of results equates more with nonobviousness rather than obviousness, whereas that which is predictable is more likely to be obvious.”). And where the prior art literature discloses some unpredictability, it is the patent challenger’s burden to show

that “a skilled artisan nevertheless would have had a reasonable expectation of success.” *Eli Lilly*, 8 F.4th at 1349. Moreover, in the context of drug development, the prior art must provide a reasonable expectation of success in achieving the invention at the specific dosage claimed. *Teva Pharms. USA, Inc. v. Corcept Therapeutics, Inc.*, 18 F.4th 1377, 1381 (Fed. Cir. 2021).

85. Mere knowledge of a goal, based on the prior art, does not equate to a reasonable expectation of successfully achieving that goal. *Abbott Lab’ys v. Sandoz, Inc.*, 544 F.3d 1341, 1352 (Fed. Cir. 2008). And “the expectation-of-success analysis must match the highly desired goal, not switch to a different goal that may be a less challenging but also less worthwhile pursuit.” *Institut Pasteur & Universite Pierre Et Marie Curie v. Focarino*, 738 F.3d 1337, 1346 (Fed. Cir. 2013).

86. In *Sanofi v. Watson Lab’ys Inc.*, the Federal Circuit affirmed the district court’s ruling that the patent challengers had failed to prove a reasonable expectation of success where the asserted references described the patentee’s completed and ongoing clinical trials, which the district court held provided merely hypotheses that would not support a reasonable expectation that the claimed drug would achieve the claimed treatment outcome. 875 F.3d 636 (Fed. Cir. 2017). There, the “key publications” described clinical trials conducted by the patentee using the claimed drug. *Id.* at 640, 648. While these studies “showed some positive results” as to one treatment outcome measure, they “were not designed to investigate” the *claimed*

outcome measure of reduced hospitalizations “let alone to do so for the patient population covered by the patent claims at issue.” *Id.* at 648. Prior art publications describing these studies noted that reduced hospitalizations was a “potential” benefit of the drug but “no more.” *Id.* at 648. Another prior art reference described the design of the clinical trial the results of which ultimately supported the challenged claim’s reduced-hospitalization outcome measure, and stated that reduced hospitalizations could be “expected” from the treatment protocol described in the clinical trial. *Id.* The district court credited the patentee’s expert’s testimony that these statements in the prior art publications describing the clinical trials “would be understood as nothing more than a statement of the hypothesis being tested” and “that a person of ordinary skill in the art would not ‘draw an expectation’ about [the claimed drug] from the post-hoc analysis,” and the Federal Circuit affirmed. *Id.*

87. Similarly, in *Eli Lilly*, 8 F.4th at 1331, the Federal Circuit held that the asserted method-of-treatment claims were limited by the preambles’ statements of “intended purpose”—treating or reducing the incidence of vasomotor symptoms—“and thus those limitations are undoubtedly relevant to the reasonable expectation of success.” *Id.* at 1345. “Lilly was required to show that a skilled artisan would have had a ‘reasonable expectation’ of success in treating vasomotor symptoms, even if such success was not guaranteed in all cases.” *Id.* The Federal Circuit went on to affirm the PTAB’s analysis that the asserted references’ lack any actual data

showing the claimed drug was efficacious for treating vasomotor symptoms, which supported the PTAB's ruling that the references would not have provided a POSA with a reasonable expectation of successfully treating vasomotor symptoms. *Id.* at 1346.

88. Likewise, in *Novartis Pharms. Corp. v. W.-Ward Pharms. Int'l Ltd.*, the Federal Circuit affirmed a ruling from this District that the patent challenger had failed to prove that a POSA would have a reasonable expectation of success where there were no publicly available clinical trial data on the use of the claimed drug to treat the specific form of cancer specified in the claims, despite the fact that there were publicly available clinical trial data showing that another compound from the same class as the claimed drug was effective in treating the same form of cancer. 923 F.3d 1051, 1060 - 62 (Fed. Cir. 2019).

2. Hindsight

89. The requirement that the patent challenger prove a motivation to combine the teachings of the asserted references with a reasonable expectation of successfully achieving the claimed invention girds against impermissible hindsight. *Cf. KSR*, 550 U.S. at 421; *Star Sci., Inc. v. R.J. Reynolds Tobacco Co.*, 655 F.3d 1364, 1375 (Fed. Cir. 2011) ("Importantly, the great challenge of the obviousness judgment is proceeding without any hint of hindsight."); *Sanofi-Synthelabo.*, 550 F.3d at 1088.

90. The Federal Circuit “ha[s] observed that ‘the prejudice of hindsight bias’ often overlooks that the ‘genius of invention is often a combination of known elements which in hindsight seems preordained.’” *Polaris*, 882 F.3d at 1068 (quoting *Power Integrations, Inc. v. Fairchild Semiconductor Int’l, Inc.*, 711 F.3d 1348, 1368 (Fed. Cir. 2013)).

91. When simplistic prior art references are asserted for proving obviousness, “the opportunity to judge by hindsight is particularly tempting.” *Polaris*, 882 F.3d at 1068 (“We have also recognized that, ‘[w]hen the art in question is relatively simple, as is the case here, the opportunity to judge by hindsight is particularly tempting.’” (quoting *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1351 (Fed. Cir. 2001))).

E. Objective Indicia of Nonobviousness

92. Objective indicia of nonobviousness, also referred to as “secondary considerations,” must be considered by the court where evidence of such indicia is presented. *See Apple Inc. v. Samsung Elecs. Co., Ltd.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016) (en banc) (“A determination of whether a patent claim is invalid as obvious under § 103 requires consideration of all four factors articulated in *Graham v. John Deere Co. of Kansas City*, and it is error to reach a conclusion of obviousness until all those factors are considered. 383 U.S. 1 (1966). Objective indicia of nonobviousness must be considered in every case where present. This

requirement is in recognition of the fact that each of the *Graham* factors helps inform the ultimate obviousness determination.” (citation omitted)). To have probative value, there must be a nexus between the claimed invention and the proffered evidence of objective indicia of nonobviousness. “[T]here is a presumption of nexus for objective considerations when the patentee shows that the asserted objective evidence is tied to a specific product and that product is the invention disclosed and claimed in the patent.” *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049, 1067 (Fed. Cir. 2020) (citation omitted), *cert. denied*, 141 S. Ct. 2623 (2021). To rebut the presumption of nexus, the patent challenger must present “evidence that shows the proffered objective evidence was ‘due to extraneous factors other than the patented invention.’” *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1329 (Fed. Cir. 2016) (quoting *Demaco, Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.3d 1387, 1393 (Fed. Cir. 1988)).

93. Similarly, evidence of objective indicia of nonobviousness must be considered together with the proffered evidence of alleged obviousness and before a determination as to obviousness is reached. *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Pat. Litig.*, 676 F.3d 1063, 1076 (Fed. Cir. 2012).

94. “It is the secondary considerations that are often the most probative and determinative of the ultimate conclusion of obviousness or nonobviousness.” *Pro-Mold & Tool Co., Inc. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir.

1996); *see also Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1365 (Fed. Cir. 2008) (objective evidence of nonobviousness “may often be the most probative and cogent evidence” available. (quoting *Catalina Lighting, Inc. v. Lamps Plus, Inc.*, 295 F.3d 1277, 1288 (Fed. Cir. 2002)); *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617 F.3d 1296, 1305 (Fed. Cir. 2010).

95. Although the patent owner bears the burden of production for objective indicia of nonobviousness, the burden of persuasion remains at all times with the patent challenger. *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1305 (Fed. Cir. 2015).

96. Objective indicia of nonobviousness may include: (a) commercial success of the invention, causally related to the invention itself rather than to companion factors, such as advertising or attractive packaging; (b) the technical direction followed by those skilled in the art taught away from the claimed

invention;³ (c) a long-felt but unsatisfied or unmet need for the invention;⁴ (d) the invention achieves results that were or are unexpected to those skilled in the art;⁵

³ *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994) (“A reference may be said to teach away when a person of ordinary skill, upon [examining] the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference’s disclosure is unlikely to be productive of the result sought by the applicant.”); *see also Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1360 (Fed. Cir. 2017); *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1326 (Fed. Cir. 2009) (“An inference of nonobviousness is especially strong where the prior art’s teachings undermine the very reason being proffered as to why a person of ordinary skill would have combined the known elements.”); *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1305 (Fed. Cir. 2015) (affirming ruling that prior art taught away from claimed invention where “known side effects would have discouraged a person of ordinary skill from using” the disclosure of the asserted prior art reference).

⁴ *WBIP*, 829 F.3d at 1332 (Fed. Cir. 2016) (“Evidence of a long felt but unresolved need tends to show non-obviousness because it is reasonable to infer that the need would have not persisted had the solution been obvious.”).

⁵ *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995) (“One way for a patent applicant to rebut a *prima facie* case of obviousness is to make a showing of ‘unexpected results,’ i.e., to show that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected. The basic principle behind this rule is straightforward—that which would have been surprising to a person of ordinary skill in a particular art would not have been obvious.”); *Millennium Pharms., Inc. v. Sandoz Inc.*, 862 F.3d 1356, 1368 (Fed. Cir. 2017) (“Unexpected results are useful to show the improved properties provided by the claimed compositions are much greater than would have been predicted.” (citation omitted)); *Honeywell Int’l Inc. v. Mexichem Amanco Holding S.A. DE C.V.*, 865 F.3d 1348, 1356 (Fed. Cir. 2017) (“Even when presenting evidence of unexpected results to ‘rebut’ an Examiner’s *prima facie* case for obviousness, a patent owner need not demonstrate that one of ordinary skill would have expected failure—rather, the patent owner need only establish that the results would have been unexpected to

(e) copying of the invention; (f) failure of others of ordinary skill in the art to make the invention;⁶ (g) skepticism on the part of those skilled in the art that the patentee's approach worked; and (h) praise for the invention.

97. Patent challengers bear the burden of demonstrating by clear and convincing evidence that a “blocking” patent existed that would reduce the probative value of evidence of commercial success, failure of others, and long-felt but unmet need. *Acorda Therapeutics, Inc. v. Roxane Lab’ys, Inc.*, 903 F.3d 1310, 1339 (Fed. Cir. 2018). “A patent has been called a ‘blocking patent’ where practice of a later invention would infringe the earlier patent.” *Id.* at 1337. Whether an alleged blocking patent diminishes the weight of evidence of commercial success, failure of others, and long-felt but unmet need is “a fact-specific inquiry,” and “the mere existence or sheer number of blocking patents does not, without more, ‘necessarily detract from evidence of commercial success[,]’” failure of others, and long-felt but

one of ordinary skill at the time of invention, or much greater than would have been predicted.” (citations and internal quotation marks omitted)).

⁶ *In re Cyclobenzaprine*, 676 F.3d at 1082 (Fed. Cir. 2012) (“The purpose of evidence of failure of others is to show ‘indirectly the presence of a significant defect in the prior art, while serving as a simulated laboratory test of the obviousness of the solution to a skilled artisan.’” (quoting *Symbol Techs. v. Opticon, Inc.*, 935 F.2d 1569, 1578–79 (Fed. Cir. 1991))); *Millennium Pharms.*, 862 F.3d at 1369 (“Although ‘[e]vidence is particularly probative of obviousness when it demonstrates both that a demand existed for the patented invention, and that others tried but failed to satisfy that demand,’ a patent owner may establish a long-felt need without presenting evidence of failure of others.” (quoting *In re Cyclobenzaprine*, 676 F.3d at 1082))).

unmet need. *Id.* at 1338 (quoting *Merck Sharp & Dohme Corp. v. Hospira, Inc.*, 874 F.3d 724, 731 (Fed. Cir. 2017)). Rather, the court must evaluate the “significance of the deterrence” provided by the allegedly blocking patent based on the evidence in the record. *Id.* at 1339.

98. In *Acorda*, the Federal Circuit specifically analyzed the following factors in determining the significance of the deterrence of the allegedly blocking patent: whether the original patent holder “sought to license the [] patent to any [other] entity”; whether the licensee sought to sublicense the patent; development activities outside the United States involving the subject matter of the claimed inventions; and the availability of the safe harbor under 35 U.S.C. § 271(e)(1) for activities undertaken “solely for uses reasonably related to the development and submission of information” to FDA. 903 F.3d at 1339–41.

99. The Federal Circuit also noted that the following additional factors may be relevant to the significance of the deterrence: the possibility of challenging the blocking patent; “the costliness of the project; the risk of research failure; the nature of improvements that might arise from the project, and whether such improvements will be entirely covered by the blocking patent; the size of the market opportunities anticipated for such improvements; the costs of arriving at the improvements and getting them to market; the risk of losing the invention race to a blocking-patent owner or licensee; the risk that the blocking-patent owner (making its own economic

calculations, perhaps in light of its own other products or research activities) will altogether refuse to grant a license to the improvement or will demand so large a share of profits that the whole project is not worthwhile for the potential innovator—all evaluated in light of other investment opportunities.” *Id.* at 1338.

100. At least one district court has also recognized that the expiration date(s) of the allegedly blocking patent(s) may be relevant in determining whether blocking patent(s) discouraged innovation. In *Janssen Pharms., Inc. v. Teva Pharms. USA, Inc.*, the court credited testimony from both parties’ experts that “the drug development process can take many years, even up to a decade or longer” in finding that allegedly blocking patents that each expired less than 10 years before the claimed priority date of the challenged patent “created little, if any, disincentives to innovate.” No. CV 18-734, 2021 WL 5323737, at *29 (D.N.J. Nov. 16, 2021).

101. Ultimately, “a court may . . . be left, for its evaluation, with the solid premise of diminished incentives, plus some evidence (possibly weak or ambiguous) about the significance of the deterrence, together with a background sense of the general realities in the area at issue that can affect the weight to be given to the evidence in the specific case.” *Acorda*, 903 F.3d at 1339.

F. Written Description

102. Section 112 states that “[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it,

in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same” 35 U.S.C. § 112(a).

103. “Invalidating a claim [for lack of written description] requires a showing by clear and convincing evidence that the written description requirement has not been satisfied.” *Invitrogen Corp. v. Clontech Lab ’ys, Inc.*, 429 F.3d 1052, 1072 (Fed. Cir. 2005).

104. Whether the written description requirement is met is a question of fact. *Alcon Rsch. Ltd. v. Barr Lab ’ys, Inc.*, 745 F.3d 1180, 1190 (Fed. Cir. 2014).

105. “The form and presentation of the description can vary with the nature of the invention; compliance with the written description requirement is a fact-dependent inquiry.” *In re Skvorecz*, 580 F.3d 1262, 1269 (Fed. Cir. 2009).

106. “The standard for satisfying the written description requirement is whether the disclosure ‘allows one skilled in the art to visualize or recognize the identity of the subject matter purportedly described.’ There is no requirement that the disclosure contain ‘either examples or an actual reduction to practice’; rather, the critical inquiry is whether the patentee has provided a description that ‘in a definite way identifies the claimed invention’ in sufficient detail that a person of ordinary skill would understand that the inventor was in possession of it at the time of filing.

That assessment ‘requires an objective inquiry into the four corners of the specification.’” *Alcon*, 745 F.3d at 1190–91 (citations omitted).

107. Actual clinical data regarding efficacy of the claimed method is not required to adequately describe a patented method of treatment and comply with the written description requirement of § 112. *See Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co.*, 276 F. Supp. 3d 629, 657 (E.D. Tex. 2017) (specification need not describe use of claimed treatment in human clinical trial to satisfy the written description requirement), *aff’d*, 739 Fed. App’x 643 (Fed. Cir. 2018) (*per curiam*); *Bone Care Int’l, LLC v. Pentech Pharms., Inc.*, 862 F. Supp. 2d 790, 809–10 (N.D. Ill. 2012) (“[T]he test under § 112 is not how much data [the specification] provides to substantiate the invention . . . , but rather what a [person of ordinary skill in the art] would understand the [specification] to reasonably convey.”).

108. The written description of a patent may incorporate by reference a U.S. patent or U.S. patent application publication that contains material that is “necessary” to “[p]rovide a written description of the claimed invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and set forth the best mode contemplated by the inventor of carrying out the invention as required by 35 U.S.C. 112(a).” 37 C.F.R. § 1.57(d)(1).

G. Enablement

109. Section 112 states that “[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same” 35 U.S.C. § 112(a).

110. “To prove that a claim is invalid for lack of enablement, a challenger must show by clear and convincing evidence that a person of ordinary skill in the art would not be able to practice the claimed invention without ‘undue experimentation.’” *Alcon*, 745 F.3d at 1188.

111. “Enablement is a question of law based on underlying factual findings.” *In re Morsa*, 713 F.3d 104, 109 (Fed. Cir. 2013).

112. “Factors to be considered in determining whether a disclosure would require undue experimentation . . . include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.” *In re Wands*, 858 F.2d at 737.

113. “The question of undue experimentation is a matter of degree, and what is required is that the amount of experimentation not be ‘unduly extensive.’ For example, the fact that a clinician’s involvement may be necessary to determine effective amounts of the single compound effervescent agent and its corresponding soluble acid source does not itself constitute undue experimentation.” *Cephalon, Inc. v. Watson Pharms., Inc.*, 707 F.3d 1330, 1338 (Fed. Cir. 2013).

114. “[A] considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance.” *Id.* at 1339.

115. “Where the specification provides ‘guidance in selecting the operating parameters that would yield the claimed result,’ it is fair to conclude that the experimentation required to make a particular embodiment is not ‘undue.’” *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1565 (Fed. Cir. 1996).

116. “It is well established that the ‘enablement requirement is met if the description enables *any* mode of making and using the invention.’” *Takeda Pharm. Co. Ltd. v. Zydus Pharms. USA, Inc.*, 743 F.3d 1359, 1369 (Fed. Cir. 2014) (emphasis in original).

117. “[A] patentee is not required to provide actual working examples . . . ‘[t]he burden is on one challenging validity to show by clear and convincing

evidence that the prophetic examples together with other parts of the specification are not enabling.” *Alcon*, 745 F.3d at 1189–90.

118. The written description of a patent may incorporate by reference a U.S. patent or U.S. patent application publication that contains material that is “necessary” to “[p]rovide a written description of the claimed invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and set forth the best mode contemplated by the inventor of carrying out the invention as required by 35 U.S.C. 112(a).” 37 C.F.R. § 1.57(d)(1).

H. Improper Inventorship

119. “Because a patent is presumed valid under 35 U.S.C. § 282, there follows a presumption that the named inventors on a patent are the true and only inventors.” *Gemstar-TV Guide Int’l, Inc. v. Int’l Trade Comm’n*, 383 F.3d 1352, 1381 (Fed. Cir. 2004). “In order to rebut this presumption, a party challenging patent validity for omission of an inventor must present clear and convincing evidence that the omitted individual actually invented the claimed invention.” *Acromed Corp. v. Sofamor Danek Grp., Inc.*, 253 F.3d 1371, 1379 (Fed. Cir. 2001).

120. Inventorship is a question of law. *Caterpillar Inc. v. Sturman Indus., Inc.*, 387 F.3d 1358, 1376 (Fed. Cir. 2004).

121. “Determining ‘inventorship’ is nothing more than determining who conceived the subject matter at issue, whether that subject matter is recited in a claim in an application or in a count of an interference.” *Sewall v. Walters*, 21 F.3d 411, 415 (Fed. Cir. 1994); *see Burroughs Wellcome Co. v. Barr Lab’ys, Inc.*, 40 F.3d 1223, 1227–28 (Fed. Cir. 1994) (“Conception is the touchstone of inventorship.”).

122. Conception is the “formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.” *Sewall* 21 F.3d at 415 (“Conception exists when a definite and permanent idea of an operative invention, including every feature of the subject matter sought to be patented, is known.”); *see also Hybritech*, 802 F.2d at 1376; *Spancion, Inc. v. Int’l Trade Comm’n*, 629 F.3d 1331, 1356 (Fed. Cir. 2010). For product-by-process claims, “[e]ach element contained in a patent claim is deemed material to defining the scope of the patented invention.” *Warner-Jenkinson*, 520 U.S. at 29. Accordingly, conception of a product-by-process claim requires conception of the process recited in the claim. *Fiers v. Revel*, 984 F.2d 1164, 1169 (Fed. Cir. 1993).

123. “Conception is complete when one of ordinary skill in the art could construct the apparatus [or product] without unduly extensive research or experimentation.” *Sewall*, 21 F.3d at 415. “An idea is sufficiently definite for conception ‘when the inventor has a specific, settled idea, a particular solution to the

problem at hand, not just a general goal or research plan he hopes to pursue.”

Spansion, 629 F.3d at 1356; see *Fiers*, 984 F.2d at 1169.

124. “Contributions to realizing an invention may not amount to a contribution to conception if they merely explain what was ‘then state of the art,’ [or] if they are too far removed from the real-world realization of an invention” *Eli Lilly & Co. v. Aradigm Corp.*, 376 F.3d 1352, 1359 (Fed. Cir. 2004).

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

VANDA PHARMACEUTICALS INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA,
INC., et al.,

Defendants.

C.A. No. 18-651-CFC
(Consolidated)

**EXHIBIT 5 – DEFENDANTS’ STATEMENT
OF CONTESTED ISSUES OF LAW**

Defendants identify the following issues of law that remain to be litigated, with citations to authorities relied upon. This statement is based on the arguments Defendants expect to make as well as their understanding of the arguments that Plaintiff is likely to make. If Plaintiff seeks to introduce different legal arguments, Defendants reserve the right to supplement this statement. If an issue identified herein is more properly considered an issue of fact, it should be so considered. If an issue of fact is more properly considered an issue of law, that issue is incorporated into this statement. The authorities cited herein are not exhaustive; Defendants may rely on authority not cited in this statement. Further, the following list of issues of law to be litigated is not intended to encompass legal arguments Defendants may make in support of or in opposition to a motion for judgment as a matter of law.

The following issues of law remain to be litigated.

I. Infringement

1. Plaintiff claims that Defendants' development, marketing, and sale of their generic Hetlioz® products (1) will directly infringe the asserted product-by-process patent claim under 35 U.S.C. § 271(a); (2) will induce infringement of the various asserted method-of-treatment claims under 35 U.S.C. § 271(b); and (3) will

contribute to the infringement of the various asserted method-of-treatment claims under 35 U.S.C. § 271(c).¹

A. Direct Infringement Under § 217(a)

2. Under 35 U.S.C. § 217(a), “whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore, infringes the patent.” Infringement under Section 271(a) is typically referred to as “direct infringement.” Direct infringement may be either literal or under the doctrine of equivalents.

3. The determination of whether an accused product or method directly infringes a patent claim has two steps: (1) construction of the claim to determine its meaning and scope and (2) comparison of the properly construed claim to the product at issue. *See Seiyaku Co., Ltd. v. Int’l Trade Comm’n*, 109 F.3d 726, 731 (Fed. Cir. 1997) (citing *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff’d*, 517 U.S. 370 (1996)).

¹ While Plaintiff also asserts (as a fourth theory) direct infringement of the asserted product-by-process patent claim under 35 U.S.C. § 271(g), *see* Plf.’s Statement of Contested Issues of Law at 11, this provision of the Patent Act pertains to infringement of *process* patents, not *product-by-process* patents. *See* 35 U.S.C. § 271(g) (“Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a *process patented* in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use . . . occurs during the term of such *process patent*.”) (emphases added).

4. The first step of the infringement analysis is determining the meaning and scope of the claims, *see Active Video Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1319 (Fed. Cir. 2012), which this Court did in its three claim-construction orders in this case (D.I. 105; D.I. 183; D.I. 230). The second step is to compare the claims as construed to the accused product to determine whether the claims read onto the accused product. *Id.* The first step is a question of law, while the second step is a question of fact. *Id.* “To prove infringement, a plaintiff must prove the presence of each and every claim element or its equivalent in the accused method or device.” *Star Sci., Inc. v. R.J. Reynolds Tobacco Co.*, 655 F.3d 1364, 1378 (Fed. Cir. 2011). If “even one claim limitation is missing or not met, there is no literal infringement.” *MicroStrategy Inc. v. Bus. Objects, S.A.*, 429 F.3d 1344, 1352 (Fed. Cir. 2005).

B. Indirect Infringement

5. There is no induced or contributory infringement without direct infringement. *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915, 921 (2014). When the asserted claim is a method claim, direct infringement requires that a single party perform all the acts or steps alleged to constitute infringement. *Id.* at 922. In Hatch-Waxman cases, when the plaintiff asserts that the defendant will induce or contribute to the infringement of a method-of-treatment claim by marketing and selling a generic drug, the plaintiff bears the burden of proving that

these activities will cause physicians to practice the steps required by the asserted method-of-treatment claim. *See generally Takeda Pharms. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625 (Fed. Cir. 2015).

1. Induced Infringement Under § 271(b)

6. “The mere existence of direct infringement by physicians, while necessary to find liability for induced infringement, is not sufficient for inducement” under § 271(b). *Id.* at 631. The plaintiff must also prove “specific intent and action to induce [direct] infringement” on the part of the defendant. *Id.* (quoting *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003)). This requires “evidence of active steps taken [by the defendant] to encourage direct infringement.” *HZNP Medicines LLC v. Actavis Labs. UT, Inc.*, 940 F.3d 680, 701 (Fed. Cir. 2019). The defendant’s “mere knowledge about a product’s characteristics or that it may be put to infringing uses is not enough.” *Id.*

7. In Hatch-Waxman cases, when a plaintiff relies on the language of the proposed generic drug label to show specific intent to induce direct infringement of a method-of-treatment claim, “the pertinent question is whether the proposed label *instructs* users [e.g., physicians] to perform the patented method.” *Grunenthal GMBH v. Alkem Labs. Ltd.*, 919 F.3d 1333, 1339 (Fed. Cir. 2019) (emphasis added); *Takeda*, 785 F.3d at 631 (“The label must encourage, recommend, or promote [direct] infringement.”).

8. The language in a generic label does not “instruct” physicians to perform a patented method of treatment unless it “specifically directs” that the “particular action, or series of actions be taken.” *Otsuka Pharm. Co., Ltd. v. Torren Pharms. Ltd, Inc.*, 99 F. Supp. 461, 493 (D.N.J. 2015). For this reason, an “inducement theory necessarily fails” if the accused language of the label merely “provides information” to physicians regarding a patented treatment method, “but stops short of prescribing a specific ‘course of action.’” *Id.*; *see, e.g., HZNP*, 940 F.3d at 702 (Fed. Cir. 2019) (finding the warnings in a generic label, which “operate[d] in an ‘if/then’ manner,” did not instruct the patented treatment method).

9. For these reasons, the plaintiff cannot prove that a generic label instructs the patented treatment method by combining “vague label language . . . with speculation about how physicians may act.” *Takeda*, 785 F.3d at 632; *see also Otsuka*, 99 F. Supp. 3d at 493 (“[I]f a patentee must engage in a ‘scholarly scavenger hunt’ through the label to identify statements that may inferentially but not inevitably tie to a physician’s thoughts or acts, the inducement theory necessarily fails.”) (quoting *United Therapeutics Corp. v. Sandoz, Inc.*, No. 12-CV-01617, 2014 WL 4259153, at *19 (D.N.J. Aug. 29, 2014)).

2. Contributory Infringement Under § 271(c)

10. To prove contributory infringement of a method-of-treatment claim in a Hatch-Waxman case, “the plaintiff must show that: (1) there is direct infringement; (2) the accused infringer will import, sell or offer to sell its ANDA Products in the United States; (3) the accused infringer is aware of the patent and knows that its product is especially made for use that infringes the patent; and (4) the product is a material part of the invention and not a staple commodity or article suitable for a substantial noninfringing use.” *Lundbeck v. Lupin Ltd.*, No. CV 18-88-LPS, 2021 WL 4944963, at *107 (D. Del. Sept. 30, 2021) (citing *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1326 (Fed. Cir. 2010)).

11. “To establish liability for contributory infringement, a patent owner must show . . . that there are no substantial noninfringing uses for the accused product.” *Grunenthal*, 919 F.3d at 1340. In Hatch-Waxman cases, courts look to the generic label for substantial noninfringing uses. *Id.* A noninfringing use is substantial “when it is not unusual, far-fetched, illusory, impractical, occasional, aberrant, or experimental.” *Id.* (citations omitted). The question “focuses on whether the accused product[] can be used for purposes *other than* infringement,” *In re Bill of Lading Transmission & Processing Sys. Pat. Litig.*, 681 F.3d 1323, 1338 (Fed. Cir. 2012) (emphasis in original), and it “takes into account not only the

use's frequency, but also the use's practicality, the invention's intended purpose, and the intended market," *Lundbeck*, 2021 WL 4944963, at *107.

II. Invalidity

12. Defendants contend that various asserted patent claims are invalid (i) as anticipated by the prior art; (ii) as anticipated by prior offer for sale, sale, or use; (iii) as obvious over the prior art; (iv) for lack of written description; (v) for lack of enablement; (vi) as indefinite; and/or (vii) for improper inventorship.

13. All patents are presumed valid. *Novo Nordisk A/S v. Caraco Pharm. Labs., Ltd.*, 719 F.3d 1346, 1352 (Fed. Cir. 2013). Defendants bear the burden of proving their invalidity defenses by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 131 S. Ct. 2238, 2242 (2011); *State Contracting & Eng'g Corp. v. Condotte Am., Inc.*, 346 F.3d 1057, 1067 (Fed. Cir. 2003). The clear-and-convincing evidence standard requires that the party bearing the burden "place in the ultimate factfinder an abiding conviction that the truth of its factual contentions are 'highly probable.'" *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984). However, "a court is not bound by the PTO's actions [in granting the patent] and must make its own independent determination of patent validity." *Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1322 (Fed. Cir. 2005). And the presumption of validity does not equate to a rule that "doubts as to patentability

should be resolved in favor of a patent applicant.” *In re Anderson*, 743 F.2d 1578, 1580 (Fed. Cir. 1984).

14. “[T]here is a public interest favoring the judicial testing of patent validity For when a patent is invalid, the public parts with the monopoly grant for no return, the public has been imposed upon and the patent clause subverted.” *United States v. Glaxo Grp. Ltd.*, 410 U.S. 52, 69 (1973); *see also Prima Tek II, L.L.C. v. Polypap, S.A.R.L.*, 412 F.3d 1284, 1289 (Fed. Cir. 2005). Invalidity of the asserted claims provides a complete defense to a charge of patent infringement. *See Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563, 1583 (Fed. Cir. 1983) (“[A]n invalid claim cannot give rise to liability for infringement.”).

15. “The presentation at trial of additional evidence that was not before the PTO does not change the presumption of validity or the standard of proof, although the burden may be more or less easily carried because of the additional evidence.” *Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1569 (Fed. Cir. 1996).

C. Person of Ordinary Skill in the Art

16. “Factors that may be considered in determining level of ordinary skill in the art include: (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6)

educational level of active workers in the field.” *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1256 (Fed. Cir. 2007).

D. Anticipation By the Prior Art

17. Defendants bear the burden of proving by clear and convincing evidence that any of the asserted claims are anticipated by the prior art. 35 U.S.C. § 102; 35 U.S.C. § 282. Anticipation is a question of fact. *See Busch v. Jones*, 184 U.S. 598, 604 (1902).

18. “[I]nvalidity by anticipation requires that the four corners of a single, prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation.” *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.d 1272, 1282 (Fed. Cir. 2000). However, “the reference need not satisfy an ipsissimis verbis test.” *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009). Moreover, “[a]s long as the reference discloses all of the claim limitations and enables the subject matter that falls within the scope of the claims at issue, the reference anticipates—no actual creation or reduction to practice is required.” *Id.* (citations and quotations omitted).

19. “[A] prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference.” *Schering Corp. v. Geneva Pharm.*,

339 F.3d 1373, 1377 (Fed. Cir. 2003); *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1352 (Fed. Cir. 2002). ““In general, a limitation or the entire invention is inherent and in the public domain if it is the ‘natural result flowing from’ the explicit disclosure of the prior art.”” *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1377 (Fed. Cir. 2005) (quoting *Schering*, 339 F.3d at 1379). “Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art.” *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999).

20. “A century-old axiom of patent law holds that a product ‘which would literally infringe if later in time anticipates if earlier.’” *Upsher-Smith Labs., Inc. v. PamLab, L.L.C.*, 412 F.3d 1319, 1322 (Fed. Cir. 2005); *see also Schering*, 339 F.3d at 1380.

21. A prior-art reference must be enabling in order to be anticipatory, but it is not “necessary that an invention disclosed in a publication shall have actually been made in order to satisfy the enablement requirement.” *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985). A reference need not enable the invention as broadly as claimed to qualify as anticipatory; it need only enable one embodiment that falls within the scope of the claimed invention. *Schering*, 339 F.3d at 1381. Post-priority date evidence may be relied upon to show that a prior-art reference

was enabling. *See id.* at 1380. The question whether the disclosure of a prior-art reference is enabling is a question of law. *Impax Labs., Inc. v. Aventis Pharm., Inc.*, 545 F.3d 1312, 1315 (Fed. Cir. 2008).

22. Secondary considerations of non-obviousness are irrelevant to anticipation. *In re Wiggins*, 488 F.2d 538, 543 (C.C.P.A. 1973); *see also Celeritas Techs., Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998) (noting that teaching away has no impact on an anticipation analysis).

E. Anticipation By Prior Offer for Sale, Sale, or Use

23. Defendants bear the burden of demonstrating by clear and convincing evidence that any of the asserted patent claims are invalid as anticipated by prior offer for sale, sale, or use. *See* 35 U.S.C. § 102; 35 U.S.C. § 282.

24. “Application of the on-sale bar under section 102(b) is a question of law based upon underlying issues of fact.” *Robotic Vision Sys., Inc. v. View Eng’g, Inc.*, 112 F.3d 1163, 1167 (Fed. Cir. 1997).

25. The Patent Act prohibits the patenting of any claimed invention that was “in public use, on sale, or otherwise available to the public before the effective filing date of the invention. 35 U.S.C. § 102(a)(1); *see Helsinn Healthcare S.A. v. Teva Pharm. U.S.A., Inc.*, 139 S. Ct. 628, 630 (2019). “[T]he on-sale bar applies when two conditions are satisfied”: (i) the invention “must be the subject of a commercial offer for sale” and (ii) “the invention must be ready for patenting.”

Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 65 (1998). “[T]he reenactment of the phrase ‘on sale’ in the AIA did not alter this meaning.” *Helsinn*, 139 S. Ct. at 630; *see also FMC Techs., Inc. v. OneSubsea IP UK Ltd.*, 2019 WL 4647274, at *3 (S.D. Tex. 2019) (noting that “prior Federal Circuit rulings addressing the ‘on sale’ bar continue to apply after enactment of the AIA”). “Accordingly, a commercial sale to a third party who is required to keep the invention confidential may place the invention ‘on sale’ under the AIA.” *Helsinn*, 139 S. Ct. at 630. Under the AIA, the invalidating sale can have been made anywhere in the world. *See* 35 U.S.C. § 102(a)(1).

26. All elements of the claim must be met in the product or process offered for sale. *Scaltech Inc. v. Retec/Tetra, L.L.C.*, 178 F.3d 1378, 1383 (Fed. Cir. 1999). However, the offer need not specifically identify all of the elements, nor must the parties to the transaction recognize or appreciate that all elements are present. *Id.*; *see also Scaltech, Inc. v. Retec/Tetra, LLC*, 269 F.3d 1321, 1329 (Fed. Cir. 2001) (“the invention that is the subject matter of the offer for sale must satisfy each claim limitation of the patent, though it may do so inherently”).

27. “[T]he question of whether an invention is the subject of a commercial offer for sale is a matter of Federal Circuit law, to be analyzed under the law of contracts as generally understood.” *Grp. One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1047 (Fed. Cir. 2001). “As a general proposition, [the Federal

Circuit] will look to the Uniform Commercial Code (‘UCC’) to define whether . . . a communication or series of communications rises to the level of a commercial offer for sale.” *Id.*; accord *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363, 1365 (Fed. Cir. 2016) (en banc); see generally *Merck & Cie v. Watson Labs., Inc.*, 822 F.3d 1347, 1351–54 (Fed. Cir. 2016).

28. There is no “blanket ‘supplier exception’ to what would otherwise constitute a commercial sale.” *Medicines Co.*, 827 F.3d at 1380. “The focus must be on the commercial character of the transaction, not solely on the identity of the participants.” *Id.*

29. There is likewise no “joint development” exception to the on-sale bar. *Brassler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 182 F.3d 888, 890 (Fed. Cir. 1999).

30. “[E]vidence that the public use or sale of the patented [invention] was primarily experimental may negate an assertion of invalidity.” *Monon Corp. v. Stoughton Trailers, Inc.*, 239 F.3d 1253, 1258 (Fed. Cir. 2001). If a patentee argues that an alleged prior offer for sale, sale, or use was incidental to an experimental use, the patentee must come forward with “full, unequivocal, and convincing” proof of the experimental nature of the use. *Smith & Griggs Mfg. Co. v. Sprague*, 123 U.S. 249, 264 (1887). The ultimate burden of persuasion remains on the patent challenger. *TP Labs., Inc. v. Prof’l Positioners, Inc.*, 724 F.2d 965, 971–72 (Fed. Cir. 1984).

31. The following factors may be considered in determining whether a given sale is commercial or experimental: “(1) the necessity for public testing, (2) the amount of control over the experiment retained by the inventor, (3) the nature of the invention, (4) the length of the test period, (5) whether payment was made, (6) whether there was a secrecy obligation, (7) whether records of the experiment were kept, (8) who conducted the experiment, (9) the degree of commercial exploitation during testing, (10) whether the invention reasonably requires evaluation under actual conditions of use, (11) whether testing was systematically performed, (12) whether the inventor continually monitored the invention during testing, and (13) the nature of contacts made with potential customers.” *Allen Eng’g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1353 (Fed. Cir. 2002) (quoting *EZ Dock v. Schafer Sys., Inc.*, 276 F.3d 1347, 1357 (Fed. Cir. 2002) (Linn, J., concurring)). The ultimate inquiry must consider the totality of the circumstances. *See Lough v. Brunswick Corp.*, 86 F.3d 1113, 1120 (Fed. Cir. 1996).

“[E]xperimentation conducted to determine whether the invention would suit a particular customer’s purposes does not fall within the experimental use exception.” *Atlanta Attachment Co. v. Leggett & Platt, Inc.*, 516 F.3d 1361, 1365–66 (Fed. Cir. 2008).

F. Obviousness

32. Defendants bear the burden of demonstrating by clear and convincing evidence that any of the asserted patent claims are invalid as obvious. 35 U.S.C. § 103; 35 U.S.C. § 282.

33. Patent claims are invalid as obvious “if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.” 35 U.S.C. § 103; *see KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 405, 421 (2007). Obviousness is a question of law that involves several underlying factual inquiries, including the scope and content of the prior art, differences between the prior art and the claims at issue, the level of ordinary skill in the art, and the presence or absence of any secondary considerations of non-obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

34. “The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR*, 550 U.S. at 416. A critical issue is whether the “improvement is more than the predictable use of prior art elements according to their established functions.” *Id.* at 417. “Common sense teaches . . . that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be

able to fit the teachings of multiple patents together like pieces of a puzzle.” *Id.* at 420; *see also Leapfrog Enters. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1161–62 (Fed. Cir. 2007).

35. Moreover, “[t]hough it is never necessary to so hold, a disclosure that anticipates under § 102 also renders the claim invalid under § 103, for anticipation is the epitome of obviousness. The reverse is not true, for the need to determine obviousness presumes anticipation is lacking.” *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983).

36. A single prior-art reference can render a claim obvious if a skilled artisan would have been motivated to modify the reference to achieve the claimed invention. *See Koninklijke Philips N.V. v. Google LLC*, 948 F.3d 1330, 1338–39, (Fed. Cir. 2020).

37. A patent claim may be found invalid as obvious if the combination of elements would have been “obvious to try.” *KSR*, 550 U.S. at 421. “When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.” *Id.* Further, “[i]f this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.” *Id.*

38. In determining whether a claimed invention is obvious, the factfinder inquires whether a person of ordinary skill in the art would have been motivated to combine the prior art in the manner claimed and would have had a reasonable expectation of success in doing so. *See Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1366 (Fed. Cir. 2016). The Federal Circuit’s “case law does not require that a particular combination must be the preferred, or the most desirable, combination described in the prior art in order to provide motivation for the current invention.” *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004). Moreover, “[c]onclusive proof of efficacy is not necessary to show obviousness. All that is required is a reasonable expectation of success.” *Hoffmann-La Roche Inc. v. Apotex Inc.*, 748 F.3d 1326, 1331 (Fed. Cir. 2014); *see also Valeant Pharm. Int’l, Inc. v. Mylan Pharm. Inc.*, 955 F.3d 25, 34 (Fed. Cir. 2020).

39. The prior art should be considered for all that it teaches and is not limited to particular embodiments it describes. *See EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985).

40. The patent holder “may rebut a *prima facie* showing of obviousness with objective indicia of nonobviousness.” *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311 (Fed. Cir. 2006). “Objective evidence of nonobviousness can include copying, long felt but unsolved need, failure of others, commercial success,

unexpected results created by the claimed invention, unexpected properties of the claimed invention, licenses showing industry respect for the invention, and skepticism of skilled artisans before the invention.” *Power Integrations, Inc. v. Fairchild Semiconductor Int’l, Inc.*, 711 F.3d 1348, 1368 (Fed. Cir. 2013).

41. If a patentee asserts long-felt need and failure of others as objective indicia of non-obviousness, the patentee must present evidence of “widespread efforts of skilled artisans” to solve the problem that were unsuccessful. *NuVasive, Inc. v. Hirshfeld*, 2021 WL 3661208, at *6 (Fed. Cir. Aug. 18, 2021).

42. Objective evidence of non-obviousness requires proof of a “nexus” with the claims and must be commensurate in scope with the claims. *See Wyers v. Master Lock*, 616 F.3d 1231, 1246 (Fed. Cir. 2010); *Asyst Techs. Inc. v. Emtrak Inc.*, 544 F.3d 1310, 1316 (Fed. Cir. 2008). The patentee has the burden of production to show the required nexus between the objective indicia and the claimed invention. *Prometheus Labs., Inc. v. Roxane Labs., Inc.*, 805 F.3d 1092, 1101–02 (Fed. Cir. 2015). For commercial success, the proponent must offer proof “[that] sales were a direct result of the unique characteristics of the claimed invention.” *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996).

43. The existence of so-called “blocking patents” can negate a finding of nexus between evidence of objective indicia and the claimed invention. *See Acorda Therapeutics, Inc. v. Roxane Labs., Inc.*, 903 F.3d 1310, 1337–42 (Fed. Cir. 2018).

A “blocking patent” is an earlier patent that would be infringed by practice of the patent in question. *Id.* at 1338. “The existence of such a blocking patent may deter non-owners and non-licensees from investing the resources needed to make, develop, and market such a later, ‘blocked’ invention, because of the risk of infringement liability and associated monetary or injunctive remedies.” *Id.* “If the later invention is eventually patented by an owner or licensee of the blocking patent, that potential deterrent effect is relevant to understanding why others had not made, developed, or marketed that ‘blocked’ invention and, hence, to evaluating objective indicia of the obviousness of the later patent.” *Id.*

44. “[A]s a theoretical matter, a blocking patent may or may not deter innovation in the blocked space by commercially motivated potential innovators other than the owners or licensees of the blocking patent. *Id.* Relevant factors include the possibility of licensing or successfully challenging the blocking patent; “the costliness of the project; the risk of research failure; the nature of improvements that might arise from the project, and whether such improvements will be entirely covered by the blocking patent; the size of the market opportunities anticipated for such improvements; the costs of arriving at the improvements and getting them to market; the risk of losing the invention race to a blocking-patent owner or licensee; the risk that the blocking-patent owner (making its own economic calculations, perhaps in light of its own other products or research

activities) will altogether refuse to grant a license to the improvement or will demand so large a share of profits that the whole project is not worthwhile for the potential innovator—all evaluated in light of other investment opportunities.” *Id.*

45. Where “the inventions represented no more than ‘the predictable use of prior art elements according to their established functions’ . . . the secondary considerations are inadequate to establish nonobviousness as a matter of law.” *Wyers*, 616 F.3d at 1246 (quoting *KSR*, 550 U.S. at 417). “[S]econdary considerations of non-obviousness . . . simply cannot overcome a strong prima facie case of obviousness.” *Id.*; *see also Leapfrog*, 485 F.3d at 1162 (“[G]iven the strength of the prima facie obviousness showing, the evidence on secondary considerations was inadequate to overcome a final conclusion [of obviousness].”).

G. Invalidity of Product-By-Process Claims

46. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself.” *In re Thorpe*, 777 F.2d 695, 698 (Fed. Cir. 1985). Accordingly, “[t]he patentability of a product does not depend on its method of production.” *Id.* “If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *Id.*; *see also Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1370 n 14 (Fed. Cir. 2009) (“Because validity is determined based on the

requirements of patentability, a patent is invalid if a product made by the process recited in a product-by-process claim is anticipated by or obvious from prior art products, even if those prior art products are made by different processes.”).

H. Written Description

47. Defendants bear the burden of demonstrating by clear and convincing evidence that any of the asserted patent claims are invalid for lack of written description. 35 U.S.C. § 112; 35 U.S.C. § 282.

48. A patent must “contain a written description of the invention, and the manner and process of making and using it” that enables a skilled artisan to practice the invention. 35 U.S.C. § 112. Section 112 contains an “enablement” requirement (the specification must enable a skilled artisan to make and use the invention) and a “written description” requirement (the specification must describe the invention in sufficient detail to demonstrate that the inventor had possession of the invention). *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1344, 1351 (Fed. Cir. 2010) (en banc). These requirements must be met as of the filing date; a patentee cannot reap the benefit of later developments. *MagSil Corp. v. Hitachi Global Storage Techs., Inc.*, 687 F.3d 1377, 1380 (Fed. Cir. 2012). And the patent must describe and enable the “full scope” of the claims. *Id.*; see *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1344 (Fed. Cir. 2005).

49. Compliance with the written-description requirement is a question of fact. *See Ariad*, 598 F.3d at 1351.

50. A patent claim is invalid if the patent does not contain an adequate written description of the claimed invention. 35 U.S.C. § 112. The written description must reasonably convey “to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Ariad*, 598 F.3d at 1351. In determining whether a specification contains an adequate written description, “one must make an ‘objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.’” *Bos. Sci. Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1366 (Fed. Cir. 2011) (citing *Ariad*, 598 F.3d at 1351). A patent may not claim an invention that is broader than the disclosure of the specification. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002). “It is the disclosures of the applications that count.” *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571 (Fed. Cir. 1997).

51. “Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed. It extends only to that which is disclosed.” *Id.* Moreover, the patentee’s arguments concerning the level of specificity required to support the claims under § 112 must be consistent with the patentee’s other arguments for patentability. *See, e.g., Nuvo*

Pharm. (Ireland) Designated Activity Co. v. Dr. Reddy's Labs. Inc., 923 F.3d 1368, 1384 (Fed. Cir. 2019).

52. “[I]t is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention.” *LizardTech*, 424 F.3d at 1345.

53. The analysis for written description “compares the claims with the invention disclosed in the specification, and if the claimed invention does not appear in the specification . . . [the claim] fails regardless of whether one of skill in the art could make or use the claimed invention.” *Ariad*, 598 F.3d at 1348. (“[M]erely drawing a fence around the outer limits of a purported genus is not an adequate substitute for describing a variety of materials constituting the genus and showing that one has invented a genus and not just a species.”).

I. Enablement

54. Defendants bear the burden of demonstrating by clear and convincing evidence that any of the asserted patent claims are invalid for lack of enablement. 35 U.S.C. § 112; 35 U.S.C. § 282.

55. A specification must ‘enable’ a person of skill in the art to make and use the claimed invention. 35 U.S.C. § 112; *see Transocean Offshore Deepwater Drilling Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1355 (Fed. Cir. 2012).

Enablement is a legal question based on underlying factual determinations.

Transocean, 699 F.3d at 1355.

56. The failure of the PTO to issue an enablement rejection during prosecution does not heighten a patent challenger's burden to prove invalidity for lack of enablement. *See AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1245 (Fed. Cir. 2003).

57. Enablement is determined as of the effective filing date of the patent's application and is assessed from the perspective of a skilled artisan. *See ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010); *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1365 (Fed. Cir. 2006). Post-filing date evidence cannot be used to fill in gaps in the state of the art. *See In re Glass*, 492 F.2d 1228, 1232 (C.C.P.A. 1974).

58. "The scope of the claims must be less than or equal to the scope of the enablement. The scope of enablement, in turn, is that which is disclosed in the specification plus the scope of what would be known to one of ordinary skill in the art without undue experimentation." *Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1195–96 (Fed. Cir. 1999).

59. "A claim is sufficiently enabled even if a considerable amount of experimentation is necessary, so long as the experimentation is merely routine, or if the specification in question provides a reasonable amount of guidance with

respect to the direction in which the experimentation should proceed.” *Vasudevan Software, Inc. v. MicroStrategy, Inc.*, 782 F.3d 671, 684 (Fed. Cir. 2015) (citation omitted); *see also Cephalon, Inc. v. Watson Pharms., Inc.*, 707 F.3d 1330, 1339 (Fed. Cir. 2013); *PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1565 (Fed. Cir. 1996).

60. Courts may consider the following factors, sometimes termed the “*Wands* factors,” in determining whether the amount of experimentation that would be required to practice the invention is “undue”: “(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.” *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). These factors “are illustrative, not mandatory. What is relevant depends on the facts.” *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991).

61. “[A] patent disclosure need not enable information within the knowledge of an ordinarily skilled artisan.” *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1254 (Fed. Cir. 2004). “Nascent technology, however, must be enabled with a specific and useful teaching. The law requires an enabling disclosure for nascent technology because a person of ordinary skill in the art has little or no

knowledge independent from the patentee's instruction. Thus, the public's end of the bargain struck by the patent system is a full enabling disclosure of the claimed technology." *Id.*

J. Improper Inventorship

62. Defendants bear the burden of demonstrating by clear and convincing evidence that any of the asserted patent claims are invalid for improper inventorship. 35 U.S.C. § 101; 35 U.S.C. § 115; 35 U.S.C. § 282; *see Caterpillar Inc. v. Sturman Indus., Inc.*, 387 F.3d 1358, 1377 (Fed. Cir. 2004). "[I]nventorship is a legal conclusion premised on underlying factual findings," and it is addressed on a claim-by-claim basis. *Egenera, Inc. v. Cisco Sys., Inc.*, 972 F.3d 1367, 1376 (Fed. Cir. 2020).

63. A patent is invalid for improper inventorship if the patent does not name the true and correct inventors of the claimed subject matter. *See* 35 U.S.C. § 101; *Trovan, Ltd. v. Sokymat SA, Irori*, 299 F.3d 1292, 1301, 63 U.S.P.Q.2d 1865 (Fed. Cir. 2002); *Belcher Pharm., LLC v. Hospira, Inc.*, 2019 WL 2503159, at *1 (D. Del. June 5, 2019); *Bd. of Trs. of Univ. of Ill. v. Micron Tech., Inc.*, 2017 WL 1164483, at *2 n.1 (C.D. Ill. Mar. 28, 2017); *see also Pannu v. Iolab Corp.*, 155 F.3d 1344, 1349 (Fed. Cir. 1998) ("[I]f nonjoinder of an actual inventor is proved by clear and convincing evidence, a patent is rendered invalid.").

64. The touchstone of inventorship is “conception,” which is defined as the “formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.” *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1063 (Fed. Cir. 2005). “An idea is sufficiently definite and permanent for conception if it provides one skilled in the art with enough guidance to understand the invention, that is, when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue.” *Id.* “The inventor must be able to describe his invention with particularity.” *Id.* “This requires both (1) the idea of the invention’s structure and (2) possession of an operative method of making it.” *Id.*

65. One who “(1) contribute[s] in some significant manner to the conception or reduction to practice of the invention, (2) make[s] a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and (3) do[es] more than merely explain to the real inventors well-known concepts and/or the current state of the art” qualifies as a joint inventor. *Pannu*, 155 F.3d at 1351. It is not necessary that each inventor “make the same type or amount of contribution to the invention” to qualify as a joint inventor. *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1460 (Fed. Cir. 1998).

66. An accused infringer who raises the defense of improper inventorship need not prove who are the true inventors of the patent; it need only prove that the named inventorship is incorrect. *See Cellular Commc'ns Equip. LLC v. HTC Corp.*, 2018 WL 4261195, at *2–3 (E.D. Tex. July 5, 2018).

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

VANDA PHARMACEUTICALS
INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA,
INC., et al.,

Defendants.

C.A. No. 18-651-CFC
(Consolidated)

Exhibit 6 – Plaintiff's Witness List

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I. FACT WITNESSES

Vanda identifies the following fact witnesses whom it may call live or by deposition at trial. This list is not a commitment that Vanda will call any particular witness at trial or a representation that any of the witnesses listed are available or will appear for trial. If any third-party witness is unavailable, Vanda reserves the right to use his or her deposition testimony. If any of Vanda's or Defendants' fact witnesses are unavailable, Vanda reserves the right to use his or her deposition testimony. Vanda also reserves the right to call any witnesses listed or called by Defendants and to revise this list in light of further rulings by the Court or any other changed circumstances. In addition, Vanda reserves the right to call any witness, whether listed below or not, to establish authenticity and/or admissibility of any trial exhibit whose authenticity or admissibility is challenged by Defendants, as rebuttal, or for impeachment.

1. Dr. Mihael H. Polymeropoulos
2. Dr. Ravi K. Pandrapragada
3. Dr. Deepak S. Phadke
4. Dr. Atul Kaushik (Teva)
5. Mr. David DeCicco (Teva)
6. Dr. Vatsal V. Shah (Teva)
7. Dr. Martin K. Ehlert (Apotex)

8. Mr. Bisht Bhupesh Singh (Apotex)

II. EXPERT WITNESSES

Vanda lists below the names of the experts it may call as live witnesses at trial. This list is not a commitment that Vanda will call any particular witness at trial or a representation that any of the witnesses listed are available or will appear for trial. The listed experts' specific expertise and qualifications are set forth in Exhibit 17 (Plaintiff's Experts' CVs) and Exhibit 18 (Defendants' Experts' CVs). Vanda may present these qualifications during trial. If any of Vanda's or Defendants' expert witnesses are unavailable, Vanda reserves the right to use his or her deposition testimony.

1. Dr. Stephen C. Bergmeier
2. Dr. Daniel Combs
3. Dr. Charles A. Czeisler
4. Dr. Henry G. Grabowski
5. Dr. Steven W. Lockley
6. Dr. Andrew Parkinson
7. Dr. Jonathan Emens (Defendants)
8. Dr. David J. Greenblatt (Defendants)
9. Dr. Robert B. Perni (Defendants)
10. Dr. John W. Winkelman (Defendants)

11. Dr. DeForest McDuff (Defendants)

12. Ms. Deborah Jaskot (Defendants)

A. Brief Statement of Experts' Qualifications and Expected Testimony

1. Dr. Stephen C. Bergmeier

(a) Background/Qualifications

Dr. Bergmeier received his Ph.D. in medicinal chemistry from the University of Michigan in 1990 and his B.S. in chemistry from Iowa State University in 1978. He is currently a professor and department chair in the Department of Chemistry and Biochemistry at Ohio University. Dr. Bergmeier has received funding from the National Institutes of Health for his academic research. He is a manuscript reviewer for numerous refereed journals, including, among others, Organic Letters, the Journal of Organic Chemistry, and the Journal of the American Chemical Society. Dr. Bergmeier also serves as a grant reviewer for multiple organizations, including the National Institutes of Health, the National Science Foundation, and the Research Corporation. He has presented his academic work both nationally and internationally, at conferences focusing on organic and synthetic chemistry. Dr. Bergmeier's research has also been published in numerous peer-reviewed articles.

(b) Expected Testimony

If called at trial, Dr. Bergmeier will testify about the subject matter discussed in his expert reports and at his deposition. He will testify that the Defendants' tasimelteon products infringe the asserted claim of the '465 patent. Dr. Bergmeier will testify about the state of the art and the knowledge and level of experience of a person of ordinary skill in the relevant field at the time of the invention of the subject matter of the '465 patent. He will also testify as to the validity of the asserted claim of the '465 patent, including that the claim is not invalid under the on-sale bar, is not invalid as obvious, and is not invalid for improper inventorship. Dr. Bergmeier will testify as to objective indicia of non-obviousness regarding the asserted claim of the '465 patent. He may also offer a critique of Defendants' experts.

2. Dr. Daniel Combs

(a) Background/Qualifications

Dr. Combs received his M.D. in 2011 from the University of Arizona College of Medicine and has been board certified by the American Board of Pediatrics in sleep medicine since 2015. He is currently a physician specializing in sleep medicine at Banner University Medical Group in Tucson, Arizona and an Assistant Professor of Pediatrics and Medicine at the University of Arizona College of Medicine. Dr. Combs is also a member of the American Academy of Sleep Medicine, is currently receiving funding for sleep-medicine-related research from the National Institutes of Health, and has previously received research funding from

the American Academy of Sleep Medicine Foundation. He is a recognized lecturer on a national and international level, having been invited to do multiple presentations on sleep medicine, and has published numerous articles in refereed journals relating to sleep medicine, including articles in *Sleep* and the *Journal of Clinical Sleep Medicine*.

(b) Expected Testimony

If called at trial, Dr. Combs will testify about the subject matter discussed in his expert reports and at his deposition. Dr. Combs will testify that the proposed labels for Defendants' generic versions of tasimelteon encourage, recommend, suggest, instruct, promote, and/or require prescribers to practice the methods set forth in the asserted method-of-treatment patent claims. Dr. Combs will also offer testimony in support of objective indicia of nonobviousness. Dr. Combs may also testify about the level of skill of an ordinary artisan as of the priority date of the asserted method-of-treatment patent claims. He may also offer a critique of Defendants' experts' opinions.

3. Dr. Charles A. Czeisler

(a) Background/Qualifications

Dr. Czeisler is the Frank Baldino, Jr., Ph.D. Professor of Sleep Medicine, Professor of Medicine and Director of the Division of Sleep Medicine at Harvard Medical School; the Chief of the Division of Sleep and Circadian Disorders in the

Departments of Medicine and Neurology and Director of the Sleep Matters Initiative at Brigham Health in Boston, Massachusetts; the Director of the Harvard Work Hours Health and Safety Group; an Affiliate Faculty Member in the Program in Neuroscience at Harvard Medical School; a Senior Faculty in the Harvard College Program in General Education, Faculty of Arts and Sciences, Harvard University; and an Associate Faculty Member in the Molecular and Cellular Biology Department, Faculty of Arts and Sciences at Harvard University. Dr. Czeisler received his bachelor's degree from Harvard College in biochemistry and molecular biology *magna cum laude* in 1974, his Ph.D. in neuro and biobehavioral sciences in 1978 from Stanford University in 1978, and his M.D. from Stanford University School of Medicine in 1981. Dr. Czeisler has been studying circadian rhythms for over 35 years. His research has resulted in more than 277 reports published in peer-reviewed journals, including in *Sleep*, *Journal of Clinical Sleep Medicine*, *Journal of the American Medical Association (JAMA)*, *The Lancet*, *New England Journal of Medicine*, *Science*, and *Nature*. He has also performed research for NASA on the work-rest schedules and sleep-wake patterns of astronauts on the Space Shuttle and the International Space Station, and has been a Team Leader on the Human Performance, Sleep and Chronobiology Team of NASA's National Space Biomedical Research Institute.

(b) Expected Testimony

If called at trial, Dr. Czeisler will testify about the subject matter addressed in his expert reports and at his deposition. Dr. Czeisler will testify about the state of the art and the knowledge and level of skill and experience of an ordinary artisan in the applicable field as of the priority date of the asserted method-of-treatment patent claims. Dr. Czeisler will testify that the patents are not obvious or anticipated, and do not lack sufficient written description or enablement. Dr. Czeisler will also testify about the objective indicia of nonobviousness of these asserted method-of-treatment patent claims. He may also offer a critique of Defendants' experts' opinions.

4. Dr. Henry G. Grabowski

(a) Background/Qualifications

Dr. Grabowski received his Ph.D. in economics from Princeton University in 1967. He is currently a professor emeritus of economics and Director of the Program in Pharmaceuticals and Health Economics at Duke University. He has published numerous articles and books on the pharmaceutical industry. His academic work has been recognized through visiting scholar appointments at institutions, including the International Institute of Management in Berlin, Germany; the Office of Health Economics in London, England; and the Health Care Financing Administration in Washington, D.C. Under a series of National Science Foundation grants,

Dr. Grabowski has examined the economics of pharmaceutical research and development and the effects of various government policy actions on drug innovation. His insights into the field of health economics are highly regarded, with Congress requesting his testimony on a variety of issues, including effective patent life and generic competition in pharmaceuticals. In addition, Dr. Grabowski's work has been used by the Congressional Budget Office to analyze the effects of the Hatch-Waxman Act on research and development returns.

(b) Expected Testimony

If called at trial, Dr. Grabowski will testify about the subject matter discussed in his expert reports and at his deposition. Dr. Grabowski will testify about the objective indicia of nonobviousness of the asserted method-of-treatment patent claims, including that Hetlloz® is a commercially successful drug. Dr. Grabowski may also offer a critique of Defendants' experts.

5. Dr. Steven W. Lockley

(a) Background/Qualifications

Dr. Lockley received his B.Sc. in Biology from the University of Manchester in 1992 and his Ph.D. in Biological Sciences from the University of Surrey in 1997. He is a neuroscientist in the Division of Sleep and Circadian Rhythms at Brigham and Women's Hospital, an Associate Professor of Medicine in the Division of Sleep Medicine at Harvard Medical School, and an Adjunct Professor and Vice-

Chancellor's Fellow in the Surrey Sleep Research Centre in the Faculty of Health and Medical Sciences at the University of Surrey. Dr. Lockley has been studying circadian rhythms for over 25 years. He has published over 150 original research reports, including in the *New England Journal of Medicine*, *Lancet*, and *JAMA*.

(b) Expected Testimony

If called at trial, Dr. Lockley will testify about the subject matter discussed in his expert reports and at his deposition. Dr. Lockley will testify about the history of research on circadian rhythm sleep disorders—specifically Non-24 Sleep-Wake Disorder—and studies investigating methods for treating Non-24. Dr. Lockley will offer testimony in support of the validity of the asserted method-of-treatment patent claims, including that the patent claims are not obvious, and may offer testimony about the level of skill of an ordinary artisan as of the priority date of the asserted method-of-treatment patent claims. Dr. Lockley may also offer a critique of Defendants' experts.

6. Dr. Andrew Parkinson

(a) Background/Qualifications

Dr. Parkinson received his B.S. *magna cum laude* in Medical Biochemistry from University of Surrey, his Ph.D. in Biological Chemistry from University of Guelph, and post-doctoral training from the Roche Institute of Molecular Biology. He has over 40 years of experience in studying drug metabolism and drug

interactions and has published over 140 scientific articles in peer-reviewed journals, including articles in *Archives of Biochemistry and Biophysics*, *Biochemical Pharmacology*, and *Drug Metabolism and Disposition* and 44 book chapters or review articles. He is a distinguished lecturer on a national and international level, having given about 350 invited presentations at scientific conferences, academic institutions, and pharmaceutical companies. He is also a member of the American Society for Pharmacology and Experimental Therapeutics, the International Society for the Study of Xenobiotics, and the Society of Toxicology.

Dr. Parkinson is currently the CEO of XPD Consulting, a company that specializes in counseling clients on drug absorption, distribution, metabolism, excretion, transport, toxicity, and drug-drug interactions, including the design and interpretation of *in vitro* drug-drug interaction studies. As Chief Scientific Officer of his former company, XenoTech (1994–2011), and as CEO of his current company, XPD Consulting (2012–present), he has written or contributed significantly to the preparation of several thousand scientific reports and expert opinions regarding drug absorption, distribution, metabolism, excretion, and drug-drug interactions for pharmaceutical clients. He is also an Adjunct Professor in the Pharmacology, Toxicology & Therapeutics department at Kansas University Medical Center and has previously served as an Assistant Professor, Associate

Professor, and a Professor in the Department of Pharmacology, Toxicology & Therapeutics at the University of Kansas Medical Center.

(b) Expected Testimony

If called at trial, Dr. Parkinson will testify about the subject matter discussed in his expert reports and at his deposition. Dr. Parkinson will testify about the state of the art and the knowledge and level of experience of a person of ordinary skill in the relevant field at the time of the invention of the asserted method-of-treatment patent claims. Dr. Parkinson will testify that the patent claims are not obvious and do not claim patent-ineligible subject matter. Dr. Parkinson may also offer testimony in support of objective indicia of nonobviousness. He may also offer a critique of Defendants' experts.

III. DEFENDANTS' OBJECTIONS TO PLAINTIFF'S WITNESS LIST

Defendants object to Plaintiff calling at trial any witness they have listed by deposition designation to the extent that the witness testifies live at trial. Defendants object to Plaintiff calling any witness in Plaintiff's control by deposition designation to the extent the witness is not unavailable within the meaning of Federal Rule of Civil Procedure 32(a)(4). Defendants incorporate by reference any objection to proposed deposition testimony of any witness listed as set forth in Defendants' objections to Plaintiff's deposition designations. Defendants object to (1) the testimony of any witness for which that witness lacks personal knowledge, (2)

testimony beyond the description set forth in Plaintiff's initial disclosures, (3) testimony beyond the scope of Plaintiff's interrogatory responses, or (4) testimony not otherwise properly disclosed under the Federal Rules of Civil Procedure.

Defendants further object to Plaintiff's witnesses' testimony to the extent the testimony is in the form of inadmissible lay opinion, including but not limited to opinion testimony of lay witnesses and any testimony that is based on scientific, technical, or other specialized knowledge that should properly be the subject of expert testimony. Fed. R. Evid. 701.

Defendants further object to Plaintiff calling any of Defendants' witnesses live at trial.

Other objections to the testimony of Plaintiff's witnesses, if any, are reserved for trial.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

VANDA PHARMACEUTICALS)	
INC.,)	
)	
Plaintiff,)	
)	C.A. No. 18-651-CFC
v.)	CONSOLIDATED
)	
TEVAPHARMACEUTICALS USA,)	
INC., etal.,)	
)	
Defendants.)	

Exhibit 7 – DEFENDANTS’ WITNESS LIST

Defendants Teva Pharmaceuticals USA, Inc., Apotex Inc., and Apotex Corp., Inc. (“Defendants”), pursuant to the Scheduling and Consolidation Order (D.I. 206 ¶ 26), submit this list of witnesses that Defendants will or may call to testify live or by deposition at trial.

Defendants reserve the right to modify or amend this list to the extent necessary to reflect any future rulings by the Court, and to supplement or amend this list to fairly respond to any new issue that Plaintiff may raise. Defendants also reserve the right to call additional witnesses live or by deposition designations (or to offer additional deposition designations from witnesses identified herein) in rebuttal to issues raised in Plaintiff’s case-in-chief or rebuttal presentations.

Defendants further reserve the right to call additional witnesses live or by deposition designation to respond to issues raised after the preparation and submission of this list, including any changes by Plaintiff to its arguments, witness lists, or other positions.

Defendants further reserve the right to call any witness live or by deposition designation for purposes of impeachment. Defendants further reserve the right to call additional witnesses live or by deposition designation (or to offer additional deposition designations from witnesses identified herein) to the extent necessary to provide foundational testimony if Plaintiff contests the authenticity or admissibility of any materials to be offered as evidence at trial.

If any witness Defendants intend to call to testify live is unavailable, Defendants reserve the right to offer deposition testimony from such witness. If any of Plaintiff's expert witnesses are not called live at trial, Defendants reserve the right to offer deposition testimony of such witness(es). Defendants further reserve the right to substitute witnesses for the listed witnesses should any listed witness become unavailable for trial. Defendants further reserve the right to call any witness listed by Plaintiff on its witness list or who otherwise appears for Plaintiff at trial. Defendants further reserve the right to use any deposition designations identified by Plaintiff as either affirmative designations or as counter- designations.

	WITNESS	WILL CALL LIVE ¹	MAYCALL LIVE	MAY CALL BY DEPOSITION
1.	Dr. JonathanEmens	X		
2.	Dr. Robert Perni	X		
3.	Dr. David Greenblatt	X		
4.	Dr. John Winkelman	X		
5.	Deborah Jaskot	X		
6.	Dr. DeForest McDuff	X		
7.	Marlene Dressman			X
8.	Natalie Farris			X
9.	John Feeney			X
10.	Louis Licamele			X
11.	Ravi Pandrapragada			X
12.	Deepak Phadke			X
13.	Mihael Polymeropoulos			X
14.	Stephen Swinton			X
15.	Any witness included on Plaintiff's witness list ²		X	X

Defendants identify the following subject matter expertise for each expert witness they intend to call at trial:

Dr. Jonathan Emens: Dr. Emens is an Associate Professor in the Department of Psychiatry and an Assistant Professor in the Department of Medicine at Oregon Health & Science University. Dr. Emens is also Deputy Chief

¹ To the extent that a witness is not available to offer live testimony, Defendants may present deposition testimony for each such witness, irrespective of whether the witness is designated as may call by deposition.

² Defendants have designated Plaintiff's witnesses as "may call live" and "may call by deposition" in the event that Plaintiff does not call witnesses live at trial or attempts to limit the scope of cross-examination to subject matter elicited during direct examination.

of Mental Health and Clinical Neurosciences at the Veterans' Affairs Portland Health Care System and an Affiliate Faculty Member at the Oregon Institute of Occupational Health Sciences. Dr. Emens is a board-certified Sleep Physician and Psychiatrist and has a Doctor of Medicine degree from the University of Massachusetts Medical School. Dr. Emens has over 25 years of experience researching sleep medicine and circadian physiology. Prior to and during medical school, he worked at Harvard Medical School and Brigham and Women's Hospital—one of the premier laboratories for the study of circadian physiology. After medical school, Dr. Emens completed his psychiatry residency with Drs. Robert Sack and Alfred Lewy at Oregon Health & Science University, who demonstrated that Non-24-Sleep-Wake Rhythm Disorder can be treated with oral melatonin. Dr. Emens previously served as the Director of the Sleep Medicine Program at the VA Portland Care system and as the Program Director of the Oregon Health & Science University Sleep Medicine Fellowship. He is an expert in the diagnosis and treatment of sleep disorders, including in the fields of circadian physiology, Circadian Rhythm Sleep Disorders and Non-24-Hour Sleep- Wake Rhythm Disorder.

Dr. Emens will offer testimony regarding the asserted method-of-treatment patents, the state of the prior art, claim construction, the knowledge of a person of skill in the art at the time of the alleged invention of the asserted method-of-

treatment patents, the differences between the prior art and the asserted claims, and the invalidity of the asserted method-of-treatment patents, as well as a critique of Dr. Czeisler's and Dr. Lockley's opinions.

Dr. Robert Perni: Dr. Perni is a Principal of JMD Pharma Creativity, LLC, which provides medicinal chemistry and drug discovery consulting services for biopharmaceutical companies. Dr. Perni is an organic and medicinal chemist with over 33 years of experience in medicinal chemistry and drug development and 30 years of management experience in the pharmaceutical industry. Since 1986, Dr. Perni has held numerous senior positions overseeing the research, development, and commercial manufacturing of drug products in the pharmaceutical industry, such as the Discovery Project Head of the hepatitis C program at Vertex Pharmaceuticals, which led to the discovery and development of IncivekTM(a protease inhibitor indicated for treating hepatitis C). Over the course of his career, Dr. Perni has overseen process development research for numerous drug candidates, where he held direct oversight responsibility for cGMP manufacturing campaigns in support of Phase I and Phase II clinical trials and gained experience writing the Drug Substance CMC section of INDs. His three decades of experience managing drug research and development projects required him to frequently interface and collaborate with team members who had educational and professional experience in relevant disciplines that fell outside of Dr. Perni's immediate

expertise. Dr. Perni has a Ph.D. in Organic Chemistry from Dartmouth College and a Bachelor of Science degree in Chemistry from Northeastern University. He is an expert in the field of medicinal chemistry, including synthetic and analytical techniques for drug development as applied in the pharmaceutical industry, with knowledge of relevant regulatory considerations concerning the approval and manufacture of pharmaceutical products.

Dr. Perni will offer testimony regarding the '465 patent and its file history (including the file histories of patents in its family chain), its specification and teachings, claim construction, the scope and content of the prior art, the differences between the prior art and the asserted claim of the '465 patent, the knowledge of a person of skill in the art at the time of the alleged invention of the '465 patent, the invalidity of the '465 patent, the lack of nexus and alleged secondary considerations, and non-infringement of the '465 patent, as well as a critique of Dr. Bergmeier's opinions.

Dr. David Greenblatt: Dr. Greenblatt holds the Louis Lasagna, M.D., Endowed Professorship in the Department of Immunology at Tufts University School of Medicine, where he is also a Professor of Psychiatry, Medicine, and Anesthesia. Dr. Greenblatt also holds an appointment as Special and Scientific Staff (Research) at Tufts Medical Center. Since 1991, Dr. Greenblatt has been Board Certified in Clinical Pharmacology by the American Board of Clinical

Pharmacology. From 1994 to 2010, he served as Chair of the Department of Pharmacology and Experimental Therapeutics at Tufts University School of Medicine. He has over 40 years of experience in molecular and clinical pharmacology. Dr. Greenblatt has also served on the editorial boards of numerous medical and scientific journals, including the Journal of Clinical Psychopharmacology, Clinical Pharmacology in Drug Development, and the Journal of Clinical Pharmacology, and he is the author of more than 1,000 publications, including more than 780 peer-reviewed original research articles, many of which pertain to drug-drug interactions and drug metabolism. Dr. Greenblatt has a Doctor of Medicine degree from the University of Massachusetts Medical School and a Bachelor of Arts degree from Amherst College. He is an expert in the field of molecular and clinical pharmacology, including drug-drug interactions and the role of cytochrome P450 enzymes in drug metabolism.

Dr. Greenblatt will offer testimony regarding the asserted method-of-treatment patents and their file histories, the state of the prior art, claim construction, the knowledge of a person of skill in the art at the time of the alleged invention of the asserted method-of-treatment patents, and the invalidity of the asserted method-of-treatment patents, as well as a critique of Dr. Parkinson's opinions.

Dr. John Winkelman: Dr. Winkelman is the Founder and Chief of the Sleep Disorders Clinical Research Program in the Massachusetts General Hospital's Department of Psychiatry. Dr. Winkelman is also a Professor of Psychiatry at Harvard Medical School, where he lectures on sleep disorders in psychiatry residency and sleep fellowship programs. Dr. Winkelman has been a physician for more than 30 years and he is board certified in Sleep Disorders Medicine and Psychiatry. He has performed both clinical work and research in these specialties for the past 25 years. Dr. Winkelman earned his Doctor of Medicine degree from Harvard Medical School and a Ph.D. in Psychobiology from Harvard University, and he completed his residency at Massachusetts General Hospital, where he served as the Chief Resident of the Clinical Psychopharmacology Unit. Dr. Winkelman also previously served as a clinical fellow at Massachusetts General Hospital in Neurology (Sleep Medicine), and he has worked in an editorial capacity for various journals oriented towards sleep disorders, such as *Frontiers in Neuroscience: Sleep and Circadian Rhythms*. Dr. Winkelman is an expert in the diagnosis and treatment of sleep disorders, including in the fields of circadian physiology, Circadian Rhythm Sleep Disorders and Non-24-Hour Sleep-Wake Rhythm Disorder.

Dr. Winkelman will offer testimony on the asserted method-of-treatment patents, the knowledge of a person of skill in the art at the time of the alleged

invention of the asserted patents, claim construction, Vanda's and Defendants' respective drug labels, non-infringement of the asserted method-of-treatment patents, as well as a critique of Dr. Combs's opinions.

Deborah Jaskot: Ms. Jaskot is a regulatory affairs consultant for clients in the pharmaceutical development sector. Ms. Jaskot previously led the U.S. Regulatory Affairs team at Teva Pharmaceuticals USA, Inc., where she worked for more than 20 years supervising the generic-drug-submission process and post-approval process, securing FDA approval for several hundred drugs and dosage forms, and assisting Teva's Legal Affairs department in designing labeling text to exclude patented uses. Ms. Jaskot has a Master's of Science in Biochemistry and a Bachelor of Science in Biochemistry from the University of Scranton. Ms. Jaskot is an expert in the FDA regulatory process, including the FDA approval process for pharmaceuticals and post-approval maintenance for FDA-approved pharmaceuticals.

Ms. Jaskot will offer testimony on the FDA drug approval process and post-approval maintenance, the FDA approval process of Vanda's Hetlioz® product, Vanda's and Defendants' respective drug labels, and non-infringement of the asserted method-of-treatment patents, as well as a critique of Dr. Combs's opinions.

Dr. DeForest McDuff: Dr. McDuff is a Partner at Insight Economics and provides consulting services in areas including economic damages and intellectual property. Dr. McDuff also serves as an Adjunct Teaching Professor in the Department of Economics at the University of North Carolina at Chapel Hill. Dr. McDuff has a Ph.D. in Economics from Princeton University, a Master's Degree in Economics from Princeton University, a Bachelor's Degree in Economics and a Bachelor's Degree in Mathematics from the University of Maryland, College Park. He has provided expert analysis in over 50 cases involving pharmaceuticals and related products on issues that included competition, economic damages, and commercial success. Dr. McDuff is an expert in the field of economic analysis and valuation, including the assessment of the commercial success of pharmaceutical products.

Dr. McDuff will offer testimony on the alleged commercial success of Vanda's Hetlioz® product, alleged secondary considerations regarding obviousness, and the blocking nature of the '529 patent, as well as a critique of Dr. Grabowski's opinions.

VANDA’S OBJECTIONS TO DEFENDANTS’ WITNESS LIST

1. Vanda objects to Defendants’ proposed use of deposition testimony for any fact witness who testifies live at trial.

2. Vanda objects to Defendants’ proposed use of deposition testimony by Stephen Swinton. Mr. Swinton’s deposition testimony pertained only to patents and claims that are no longer being asserted in this case, including U.S. Patent No. 10,071,977 (the “’977 patent”) and claim 11 of the ’465 patent, and therefore such testimony is irrelevant.

3. Vanda objects to Defendants’ proposed use of deposition testimony by Deepak Phadke or Ravi Pandrapragada on the subject matter no longer asserted in this case, including the ’977 patent and claim 11 of the ’465 patent, and therefore such testimony is irrelevant.

4. Vanda objects to Dr. Perni providing testimony or opinion related to patents and claims no longer asserted in this case, including the ’977 patent and claim 11 of the ’465 patent, and therefore such testimony is irrelevant.

5. Vanda objects to any testimony or opinion of Ms. Jaskot related to how doctors prescribing tasimelteon would understand Vanda’s and Defendants’ labels, as Ms. Jaskot is not qualified to offer such testimony or opinions. Vanda further objects to any testimony or opinion of Ms. Jaskot as to Defendants’ state of mind regarding induced infringement of the asserted method-of-treatment claims.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

VANDA PHARMACEUTICALS INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA,
INC., et al.,

Defendants.

C.A. No. 18-651-CFC
(Consolidated)

Exhibit 8 – Plaintiff’s Deposition Designations

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DAVID DeCICCO (TEVA)
November 12, 2019 Deposition

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
7:15-17	I			
8:21-9:1				
9:3-18				
9:21-13:8	I	13:9-11	Colloquy	
13:12	I	13:9-11	Colloquy	
15:11-17:5	MIS, R, 403			
17:8-12				
17:14-18:13				
18:15-20:7	I, S, F	20:8-12	NR, 602	
20:12-23:23	I	20:8-12	NR, 602	
26:16-21				
27:12-28:7				
28:18-24		28:9-17	NR, 602	

Plaintiff's Objection Key

403: Prejudicial, confusing, and/or waste of time
602: Lack of foundation
701: Opinion testimony by lay witness
Colloquy: Attorney colloquy or objection
NR: Not related
I: Incomplete

Defendants' Objection Key

403: Prejudicial
V: Vague and ambiguous
AF: Assuming facts not in evidence
E or 701 or 702/703: Calls for expert opinion, improper testimony of a lay witness
F or 602: Lacks foundation
H or 802: Hearsay

HYP: Improper hypothetical
I: Incomplete
MIS: Mischaracterizes evidence/ testimony or is misleading
OBJ: Includes attorney objections
R or 402 or NR: Relevance
S: Calls for speculation

C: Compound
Scope: Outside the scope of 30(b)(6) designation
NQP or MA: No question posed
NA: No answer
A&A: Asked and answered
NS: Nonsensical

DAVID DeCICCO (TEVA; CONTINUED)
November 12, 2019 Deposition

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
29:11-19				
29:21-30:11	I			
30:18-31:6	R, F, 403	31:16-23, 36:16-18, 36:25-37:1	I	33:6-9
31:13-14	R, F, 403	31:16-23, 36:16-18, 36:25-37:1	I	33:6-9
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35:10-24				
37:2-8				
37:10-38:16				
38:22-39:3	R, 403	39:4-6, 40:10-16		
39:7-8	R, 403	39:4-6, 40:10-16		
39:15-16	R, 403	39:4-6, 40:10-16		
44:9-12				
44:14-45:13				
46:11-23				

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DAVID DeCICCO (TEVA; CONTINUED)
November 12, 2019 Deposition

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
48:2-16				
48:20-24				
50:11-19	F, E	49:25-50:6, 50:8-9, 61:8-10, 61:13-22, 61:25-62:4, 62:7-12, 63:3-4, 63:7-8	I, NR	49:14-19, 49:21-22, 49:24
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54:10-12	S, F, E	49:25-50:6, 50:8-9,	I, NR	49:14-19, 49:21-22,

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NA: No answer
A&A: Asked and answered
NS: Nonsensical

DAVID DeCICCO (TEVA; CONTINUED)**November 12, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		61:8-10, 61:13-22, 61:25-62:4, 62:7-12, 63:3-4, 63:7-8		49:24
54:14-15	S, F, E	49:25-50:6, 50:8-9, 61:8-10, 61:13-22, 61:25-62:4, 62:7-12, 63:3-4, 63:7-8	I, NR	49:14-19, 49:21-22, 49:24
54:17-18	S, F, V, E	49:25-50:6, 50:8-9, 61:8-10, 61:13-22, 61:25-62:4, 62:7-12, 63:3-4, 63:7-8	I, NR	49:14-19, 49:21-22, 49:24
54:20-55:7	S, F, E	49:25-50:6, 50:8-9, 61:8-10, 61:13-22, 61:25-62:4, 62:7-12, 63:3-4, 63:7-8	I, NR	49:14-19, 49:21-22, 49:24
55:10-11	S, F, V, E	49:25-50:6, 50:8-9, 61:8-10, 61:13-22, 61:25-62:4, 62:7-12, 63:3-4, 63:7-8	I, NR	49:14-19, 49:21-22, 49:24

Plaintiff's Objection Key

403: Prejudicial, confusing, and/or waste of time
602: Lack of foundation
701: Opinion testimony by lay witness
Colloquy: Attorney colloquy or objection
NR: Not related
I: Incomplete

Defendants' Objection Key

403: Prejudicial
V: Vague and ambiguous
AF: Assuming facts not in evidence
E or 701 or 702/703: Calls for expert opinion, improper testimony of a lay witness
F or 602: Lacks foundation
H or 802: Hearsay

HYP: Improper hypothetical
I: Incomplete
MIS: Mischaracterizes evidence/ testimony or is misleading
OBJ: Includes attorney objections
R or 402 or NR: Relevance
S: Calls for speculation

C: Compound
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DAVID DeCICCO (TEVA; CONTINUED)
November 12, 2019 Deposition

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
56:13–19				
57:13–16	S, F, V, R, 403, E	49:25–50:6, 50:8–9, 61:8–10, 61:13–22, 61:25–62:4, 62:7–12, 63:3–4, 63:7–8	I, NR	49:14–19, 49:21–22, 49:24
57:19	S, F, V, R, 403, E	49:25–50:6, 50:8–9, 61:8–10, 61:13–22, 61:25–62:4, 62:7–12, 63:3–4, 63:7–8	I, NR	49:14–19, 49:21–22, 49:24
59:5–13	I, S			
63:21–64:3	S, F, V, E			
64:6–8	S, F, V, E			
65:5–8				
65:10–25				
66:12–67:22	S, V			
67:24–25	F			
68:2–4	F			

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DAVID DeCICCO (TEVA; CONTINUED)**November 12, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
68:7-9	F			
69:17-70:1				
70:5-71:25	S, F	72:2-9	I	72:10-73:3
73:4-8	I, R, 403	72:2-9	I	72:10-73:3
73:16-74:10	S, F			
74:22-75:21				
76:8-12	MIS, S, F, V			
76:14-15	S, F			
102:8-11				
102:13-18				
103:7-23				
104:7-24				

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DAVID DeCICCO (TEVA)
December 10, 2020 Deposition

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
6:1-6				
7:21-9:9				
9:15-25	F, R, 403	10:1, 10:4	I	10:10-11, 10:16
10:5-9				
16:4-10				
18:1-10				
24:20-25:2				
25:14-20	I, F	25:21		
28:6-10	F			

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DAVID DeCICCO (TEVA)
August 17, 2021 Deposition

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
5:20-22				
6:2-25				
7:2-3				
7:24-25				
8:2-3				
8:8-12				
8:14-22				
11:13-23				
12:3-7	C, F			
12:9-21	I, S	12:24-25		
13:4-7	I, V, S	13:9		
13:10-13				
13:24-25	V, S			

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DAVID DeCICCO (TEVA; CONTINUED)**August 17, 2021 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
14:2–3	V, S			
14:10–14	V, S			
14:16–18	F			

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ATUL KAUSHIK (TEVA)
November 5, 2019 Deposition

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
5:9–11				
7:10–16				
9:8–25				
10:9–16	MIS			
10:21–25				
31:18–25	402; NR			
32:2–25	402; NR; I			
33:2–25	402; NR; I			
34:2–24	402; NR; 403; I; OBJ	34:25–35:10	403, I, NR	
35:11–15	402			
35:21–25	402; NR; I	34:25–35:10	403, I, NR	
36:2	402; NR; I			

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ATUL KAUSHIK (TEVA; CONTINUED)**November 5, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
36:22–25	402; NR; 802; 602; I			
37:2	402; NR; 802; 602; I			
37:4–13	402; NR; 802; 602; I			
39:3–20	402; NR; 602			
40:8–15	I	40:16		
40:23–25	I; 602; 403			
41:2	I; 602; 403			
41:5–10	I			
41:22–23	I; 403			
42:9–15	I; 602; S			
42:18–22	I; 602			
43:19–25	I			
44:2–25	I; 602; NR			
45:2–6	I; 602; NR			
46:23–25	I; 701; 702/703			

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ATUL KAUSHIK (TEVA; CONTINUED)**November 5, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
47:2–25	I; 701; 702/703			
48:2–3	I; 701; 702/703			
51:2–15	403; 602; S			
51:18–22	I; 403; V			
51:24–25	I			
52:2–25	I; 403; 602			
53:2–14	I; 602; 701; S			
53:25	I; 602; 701; S			
54:2–3	I; 602; 701; S			
54:6–25	I; 602; 701			
55:2–4	I; 602; S			
55:7–25	602			
56:2–9	701; 702/703; Scope; E			
56:13–15	701; 702/703; Scope; E			

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ATUL KAUSHIK (TEVA; CONTINUED)**November 5, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
56:18–19	701; 702/703; Scope; E	56:20–21 56:24–57:4	403, I	
62:4–25	I; 701			
63:2–25	I; 701			
64:2–9		64:10–15	403, I	64:16–25, 65:2–3
65:4–25	I; 602	64:10–15	403, I	64:16–25, 65:2–3
66:2–25	I; 602	64:10–15	403, I	64:16–25, 65:2–3
67:2–3	I; 602			
67:6–25	I			
68:2–25	I; 403; V	69:12–18	403, I	69:19–25, 70:2–7
69:2–11	I	69:12–18	403, I	69:19–25, 70:2–7
70:8–21	701; 702/703; V	69:12–18 70:22–24 71:2–5 79:9–10 79:12	403, I, NR	69:19–25, 70:2–7, 71:6–9, 71:15, 71:24– 25, 72:2–8 79:5–8

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ATUL KAUSHIK (TEVA; CONTINUED)**November 5, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
71:18–23	602; 403	69:12–18 70:22–24 71:2–5 79:9–10 79:12	403, I, NR	69:19–25, 70:2–7, 71:6–9, 71:15, 71:24– 25, 72:2–8, 79:5–8
72:13–15	403; 602; V; S	69:12–18 70:22–24 71:2–5 79:9–10 79:12	403, I, NR	69:19–25, 70:2–7, 71:6–9, 71:15, 71:24– 25, 72:2–8, 79:5–8
72:18–25	I; 403; 602; V; S	69:12–18 70:22–24 71:2–5 79:9–10 79:12	403, I, NR	69:19–25, 70:2–7, 71:6–9, 71:15, 71:24– 25, 72:2–8, 79:5–8
73:4–18	I; 403; 602	69:12–18 70:22–24	403, I, NR	69:19–25, 70:2–7, 71:6–9, 71:15, 71:24–

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ATUL KAUSHIK (TEVA; CONTINUED)**November 5, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		71:2-5 79:9-10 79:12		25, 72:2-8, 79:5-8
74:5-7	I	79:9-10 79:12	403, I, NR	79:5-8
74:10-12				
74:15-18				
74:21-22		74:23-75:3	403, I	75:4-6
75:7-24	I			
76:2-5				
76:9-15	602	76:16-21	403, I	
76:22-25	I; 602	76:16-21	403, I	
77:2-11	I; 602	76:16-21	403, I	
77:19-25	I; 602; 403; Scope			
78:2-4	I; 602; 403; Scope			
78:7-13	602			

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ATUL KAUSHIK (TEVA; CONTINUED)**November 5, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
78:16–25	602			
78:2–4	602; I			
82:4–7		82:8–83:15	403, I	83:16–25, 84:2–15, 84:20–25, 85:3–17
85:18–21	602; 403	82:8–83:15	403, I, NR	83:16–25, 84:2–15, 84:20–25, 85:3–17
85:23–25	I; 602; 403; NR	82:8–83:15	403, I, NR	83:16–25, 84:2–15, 84:20–25, 85:3–17
86:2–6	I; 602; 403; NR	82:8–83:15	403, I, NR	83:16–25, 84:2–15, 84:20–25, 85:3–17
86:17–25	602			
87:2–3	I; 602; OBJ	87:4–14	403, I	88:2–25
87:15–17	NQP; MA; NA; I; 602; F; S	87:18–25 89:2–24 98:16–99:6 101:11–24 103:6–9	Colloquy, 403, I, NR	88:2–25, 89:25, 90:2–5, 99:7–11, 99:19–25, 100:2–3, 100:18:25, 101:2–10, 101:25, 102:2–25, 103:2–5, 103:10–25, 104:2–14,

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ATUL KAUSHIK (TEVA; CONTINUED)**November 5, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		104:15–22 137:17–21 138:15–18 139:16–140:7		104:23–25, 105:2–8, 136:2–19, 136:22–25, 137:2–16, 137:23–25, 138:2–14, 138:21–23, 139:5–15
105:9–23	602; 402; NR			
106:4–20	602; 402; NR			
107:3–25	I; 402; NR	109:4–13 119:24–120:2 120:5–10 153:11–13 153:15–20 153:23–154:18	403, I, NR	108:25, 109:14–20, 152:23–25, 153:2–10
108:2–11	I; 402; 403; NR	109:4–13 119:24–120:2 120:5–10 153:11–13 153:15–20	403, I, NR	152:23–25, 153:2–10

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ATUL KAUSHIK (TEVA; CONTINUED)**November 5, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		153:23–154:18		
108:13–24	I; 802; 402; 403; NR	109:4–13 119:24–120:2 120:5–10 153:11–13 153:15–20 153:23–154:18	403, I, NR	152:23–25, 153:2–10
110:15–25	402; NR	109:4–13 109:21–110:14 119:24–120:2 120:5–10 153:11–13 153:15–20 153:23–154:18	403, I, NR	152:23–25, 153:2–10
111:17–25	402; NR	109:21–110:14 119:24–120:2 120:5–10	403, I, NR	152:23–25, 153:2–10

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ATUL KAUSHIK (TEVA; CONTINUED)**November 5, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		153:11-13 153:15-20 153:23-154:18		
112:2-8				
112:15-19				
113:5-23		109:4-13 109:21-110:14 119:24-120:2 120:5-10 153:11-13 153:15-20 153:23-154:18	403, I, NR	152:23-25, 153:2-10
114:8-25		109:4-13 109:21-110:14 119:24-120:2 120:5-10 153:11-13	403, I, NR	152:23-25, 153:2-10

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ATUL KAUSHIK (TEVA; CONTINUED)**November 5, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		153:15–20 153:23–154:18		
115:2–11	802	109:4–13 109:21–110:14 119:24–120:2 120:5–10 153:11–13 153:15–20 153:23–154:18	403, I, NR	152:23–25, 153:2–10
115:14–25	802	109:4–13 109:21–110:14 119:24–120:2 120:5–10 153:11–13 153:15–20 153:23–154:18	403, I, NR	152:23–25, 153:2–10
116:2–25	802; NQP; 602; F; S	109:4–13	Colloquy, 403, I, NR	152:23–25, 153:2–10

Plaintiff's Objection Key

403: Prejudicial, confusing, and/or waste of time
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ATUL KAUSHIK (TEVA; CONTINUED)**November 5, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		109:21–110:14 119:24–120:2 120:5–10 117:3–5 117:8–9 119:24–120:2 120:5–10 153:11–13 153:15–20 153:23–154:18		
117:2	I; NQP; 602; F; S	117:3–5 117:8–9	Colloquy, 403, I	
117:10–19		109:4–13 109:21–110:14 117:20–25 153:11–13 153:15–20	403, I, NR	152:23–25, 153:2–10

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Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		153:23–154:18 119:24–120:2 120:5–10		
118:2–5	403			
118:7–25	403	109:4–13 109:21–110:14 119:24–120:2 120:5–10 153:11–13 153:15–20 153:23–154:18	403, I, NR	152:23–25, 153:2–10
119:2–23	NR; 402	109:4–13 109:21–110:14 119:24–120:2 120:5–10 153:11–13 153:15–20	403, I, NR	152:23–25, 153:2–10

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Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		153:23–154:18		
120:14–16	NQP; NA; 602; F; S	120:17–121:4 122:17–123:5 153:11–13 153:15–20 153:23–154:18	403, I, NR	152:23–25, 153:2–10
121:5–20	403; 602; F; S	120:17–121:4 121:21–22 122:17–123:5 153:11–13 153:15–20 153:23–154:18	403, I, NR	152:23–25, 153:2–10
121:23–25	403; 602; F; S	120:17–121:4 121:21–22 122:17–123:5 153:11–13 153:15–20	403, I, NR	152:23–25, 153:2–10

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Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		153:23–154:18		
122:2–4	403; 602; F; S	120:17–121:4 121:21–22 122:17–123:5 153:11–13 153:15–20 153:23–154:18	403, I, NR	152:23–25, 153:2–10
123:10–25	NA; 602; F; S	120:17–121:4 121:21–22 122:17–123:5 153:11–13 153:15–20 153:23–154:18	403, I, NR	152:23–25, 153:2–10
124:2–25	I; 602; F; S	120:17–121:4 121:21–22 122:17–123:5 153:11–13	403, I, NR	152:23–25, 153:2–10

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Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		153:15–20 153:23–154:18		
125:2–19	702/703; 701; 602; S; F; E	120:17–121:4 121:21–22 122:17–123:5 153:11–13 153:15–20 153:23–154:18	403, I, NR	152:23–25, 153:2–10
126:2–14	I; 702/703; 701; 602; S; F; E	120:17–121:4 121:21–22 122:17–123:5 126:15–23 153:11–13 153:15–20 153:23–154:18	403, I, NR	126:24–25, 127:4–5, 152:23–25, 153:2–10
127:6–25	I; 802	109:4–13 109:21–110:14	403, I, NR	152:23–25, 153:2–10

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Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		119:24–120:2 120:5–10 153:11–13 153:15–20 153:23–154:18		
128:2–20	602; 702/703; 403	109:4–13 109:21–110:14 119:24–120:2 120:5–10 153:11–13 153:15–20 153:23–154:18	403, I, NR	152:23–25, 153:2–10
128:23–25	I; 602; 702/703; 403			
129:2–14	I; NA; 602	109:4–13 109:21–110:14 119:24–120:2 120:5–10	403, I, NR	152:23–25, 153:2–10

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Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		153:11-13 153:15-20 153:23-154:18		
129:17-25	I; NA; 602	109:4-13 109:21-110:14 119:24-120:2 120:5-10 153:11-13 153:15-20 153:23-154:18	403, I, NR	152:23-25, 153:2-10
130:2-25	I; 402	109:4-13 109:21-110:14 119:24-120:2 120:5-10 153:11-13 153:15-20 153:23-154:18	403, I, NR	152:23-25, 153:2-10

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Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
131:2-10	I; 402; 602	109:4-13 109:21-110:14 119:24-120:2 120:5-10 153:11-13 153:15-20 153:23-154:18	403, I, NR	152:23-25, 153:2-10
131:13-25	I; 402; 602	109:4-13 109:21-110:14 119:24-120:2 120:5-10 153:11-13 153:15-20 153:23-154:18	403, I, NR	152:23-25, 153:2-10
132:2-11	I; 402; 403	109:4-13 109:21-110:14 119:24-120:2	403, I, NR	152:23-25, 153:2-10

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Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		120:5–10 153:11–13 153:15–20 153:23–154:18		
132:14–15	I; 402; 403	109:4–13 109:21–110:14 119:24–120:2 120:5–10 132:16–20 132:25–133:18 153:11–13 153:15–20 153:23–154:18	403, I, NR	145:8–10, 145:12–20, 145:22–25, 146:2–10, 146:13–17, 146:20– 21, 152:23–25, 153:2–10
140:14–16	403; 602	141:16–142:15 153:11–13 153:15–20 153:23–154:18	403, I, NR	140:25, 141:2–15, 145:8–10, 145:12–20, 145:22–25, 146:2–10, 146:13–17, 146:20– 21, 152:23–25,

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ATUL KAUSHIK (TEVA; CONTINUED)**November 5, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		263:14-21		153:2-10
140:18-24	403; 602	141:16-142:15 153:11-13 153:15-20 153:23-154:18 263:14-21	403, I, NR	140:25, 141:2-15, 145:8-10, 145:12-20, 145:22-25, 146:2-10, 146:13-17, 146:20-21, 152:23-25, 153:2-10
146:22-25	I; 402	153:11-13 153:15-20 153:23-154:18	403, I, NR	152:23-25, 153:2-10
147:2-25	I; 402	153:11-13 153:15-20 153:23-154:18	403, I, NR	152:23-25, 153:2-10
148:2-25	I; 402	153:11-13 153:15-20 153:23-154:18	403, I, NR	152:23-25, 153:2-10
149:2-20	I; 402; 403	153:11-13	403, I, NR	152:23-25, 153:2-10

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		153:15–20 153:23–154:18		
149:25	I	153:11–13 153:15–20 153:23–154:18	403, I, NR	152:23–25, 153:2–10
150:2–12	NQP; 602; F; S	153:11–13 153:15–20 153:23–154:18	403, I, NR	152:23–25, 153:2–10
154:19–25		153:11–13 153:15–20 153:23–154:18	403, I, NR	152:23–25, 153:2–10
155:2–11	I	153:11–13 153:15–20 153:23–154:18 155:15–19 157:8–11 157:15–19	403, I, NR	152:23–25, 153:2–10, 155:20–25

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156:2–25	I	157:8–11 157:15–19	403, I	
157:2–7	I; NQP; 602; F; S	157:8–11 157:15–19	403, I	
159:10–25	I; 602; F; S	157:8–11 157:15–19	403, I, NR	
160:2–24	I; 602; F; S	157:8–11 157:15–19	403, I, NR	
162:2–25	602; F; S	157:8–11 157:15–19	403, I, NR	
163:2–25	602; F; S	157:8–11 157:15–19 164:7–8 164:10–24 165:4–13 169:22–24 170:2–6	403, I, NR	169:5–13, 169:15–21, 170:20–25, 171:6–9

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		170:9-11 171:2-5		
164:2-6	I	164:7-8 164:10-24 165:4-13 169:22-24 170:2-6 170:9-11 171:2-5	403, I, NR	169:5-13, 169:15-21, 170:20-25, 171:6-9
165:15-19	I; NQP	164:7-8 164:10-24 165:4-13 169:22-24 170:2-6 170:9-11 171:2-5	403, I, NR	169:5-13, 169:15-21, 170:20-25, 171:6-9
165:22-25		164:7-8	403, I, NR	169:5-13, 169:15-21,

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		164:10-24 165:4-13 169:22-24 170:2-6 170:9-11 171:2-5		170:20-25, 171:6-9
166:2-11		164:7-8 164:10-24 165:4-13 169:22-24 170:2-6 170:9-11 171:2-5	403, I, NR	169:5-13, 169:15-21, 170:20-25, 171:6-9
166:20-21	E; S; 701; 702/703	164:7-8 164:10-24 165:4-13 169:22-24	403, I, NR	169:5-13, 169:15-21, 170:20-25, 171:6-9

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		170:2-6 170:9-11 171:2-5		
166:23-25	I; E; S; 701; 702/703	164:7-8 164:10-24 165:4-13 169:22-24 170:2-6 170:9-11 171:2-5	403, I, NR	169:5-13, 169:15-21, 170:20-25, 171:6-9
167:2-25	I; E; S; 701; 702/703	164:7-8 164:10-24 165:4-13 169:22-24 170:2-6 170:9-11 171:2-5	403, I, NR	169:5-13, 169:15-21, 170:20-25, 171:6-9

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ATUL KAUSHIK (TEVA; CONTINUED)**November 5, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
168:2–25	I; E; S; 701; 702/703	164:7–8 164:10–24 165:4–13 169:22–24 170:2–6 170:9–11 171:2–5	403, I, NR	169:5–13, 169:15–21, 170:20–25, 171:6–9
169:2–4	I; E; S; 701; 702/703	164:7–8 164:10–24 165:4–13 169:22–24 170:2–6 170:9–11 171:2–5	403, I, NR	169:5–13, 169:15–21, 170:20–25, 171:6–9
170:12–14	NQP; F; 602; S	171:24–172:3	403, I	172:24–25, 173:2–7
171:10–23	602; F; S	171:24–172:3	403, I	172:24–25, 173:2–7
172:4–5	602; F; S	171:24–172:3	403, I	172:24–25, 173:2–7

Plaintiff's Objection Key

403: Prejudicial, confusing, and/or waste of time
602: Lack of foundation
701: Opinion testimony by lay witness
Colloquy: Attorney colloquy or objection
NR: Not related
I: Incomplete

Defendants' Objection Key

403: Prejudicial
V: Vague and ambiguous
AF: Assuming facts not in evidence
E or 701 or 702/703: Calls for expert opinion,
improper testimony of a lay witness
F or 602: Lacks foundation
H or 802: Hearsay

HYP: Improper hypothetical
I: Incomplete
MIS: Mischaracterizes evidence/
testimony or is misleading
OBJ: Includes attorney objections
R or 402 or NR: Relevance
S: Calls for speculation

C: Compound
Scope: Outside the scope of
30(b)(6) designation
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ATUL KAUSHIK (TEVA; CONTINUED)**November 5, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
172:10–12	602; F; S	171:24–172:3 172:13–14 172:17–19	403, I	172:24–25, 173:2–7
175:10–16	403	175:17	Colloquy, 403, I	
175:18–23				
176:6–15	403; 602			
176:17–25	I			
177:2–25	I			
178:2–18	I	178:20–22	403, I	
178:23–25	I	178:20–22	403, I	
179:3–23	I			
180:2–3	403; V; 602	180:17–19 180:22–23	403, I	
180:5–11	403	180:17–19 180:22–23	403, I	
180:24–25	I	180:17–19	403, I	

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Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		180:22-23		
181:2-7	I; 602; 701; E; 702/703	180:17-19 180:22-23	403, I, NR	
181:14-17	602; 701; E; 702/703			
181:20-23	602; 701; E; 702/703			
182:2-21	I; 602; 701; E; 702/703	182:22-23	403, I	
182:24-25	I; 602			
183:4-25	602; 701; F; 702/703; E			
184:2-25	I			
185:2	I; V; S			
185:4-25	602			
186:9-11	602			
186:13-18	602			
187:7-25				

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ATUL KAUSHIK (TEVA; CONTINUED)**November 5, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
188:2–25				
189:2–24	701; 702/703			
190:2–25	701; 702/703; NR; 402			
191:2–25	402; NR			
192:2–4	OBJ			
192:6–13				
192:16–24	701; 702/703			
193:2–9	701; 702/703			
193:12–25	701; 702/703			
194:2–21	701; 702/703; NQP; 602; F; S	194:22–25	403, I	
195:5–25	I; 602; F; S	194:22–25 199:16–25	403, I, NR	
196:2–25	I; 602; 701; 702/703; 602; F; S	194:22–25 199:16–25	403, I, NR	

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Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
197:2–11	I; 403; 701; 702/703; 602; F; S	194:22–25 199:16–25	403, I, NR	
197:15–25	I; 403; 701; 702/703; 602; F; S	194:22–25 199:16–25	403, I, NR	
198:2–6	I; 602; F; S	194:22–25 199:16–25	403, I, NR	
198:13–22	403; 701; 702/703; 602; F; S	194:22–25 199:16–25	403, I, NR	
198:24–25	I; 403; 701; 702/703; 602; F; S	194:22–25 199:16–25	403, I, NR	
199:2–15	I; 402; 602; F; S	194:22–25 199:16–25	403, I, NR	
200:5–10	402; 701; 702/703; I; 602; F; S	194:22–25 199:16–25 200:2–4 200:11–12	Colloquy, 403, I, NR	
200:13–25	I; 402; 701; 702/703;	194:22–25	Colloquy, 403, I, NR	

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ATUL KAUSHIK (TEVA; CONTINUED)**November 5, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
	602; F; S	199:16–25 200:2–4 200:11–12		
201:2–24	I; 402; 701; 702/703; 602; F; S	194:22–25 199:16–25	403, I, NR	
202:6–14	602; F; S	194:22–25 199:16–25	403, I, NR	
202:18–24	602; F; S	194:22–25 199:16–25	403, I, NR	
203:2–25	I; 602; F; S	194:22–25 199:16–25	403, I, NR	
204:2–25	602; F; S	194:22–25 199:16–25	403, I, NR	
205:2–25	I; 602; F; S	194:22–25 199:16–25	403, I, NR	
206:2–25	702/703; 602; F; S	194:22–25 199:16–25	403, I, NR	

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ATUL KAUSHIK (TEVA; CONTINUED)**November 5, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
207:2–25	702/703; 602; F; S	194:22–25 199:16–25	403, I, NR	
208:2–24	702/703; 602; F; S	194:22–25 199:16–25	403, I, NR	
209:21–25	I, NQP, 602; F; S			
210:2–25	I			
211:2–23		211:24–212:6	403, I	
212:7–18	V	211:24–212:6	403, I	
212:21–25				
213:2–8		213:9–12	403, I	
213:13–25				
214:2–10		214:11–20	403, I	
217:10–19	602	109:4–13 119:24–120:2 120:5–10 153:11–13	403, I, NR	108:25, 109:14–20, 152:23–25, 153:2–10

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ATUL KAUSHIK (TEVA; CONTINUED)**November 5, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		153:15–20 153:23–154:18 214:11–217:9		
217:22–25		109:4–13 119:24–120:2 120:5–10 153:11–13 153:15–20 153:23–154:18	403, I, NR	108:25, 109:14–20, 152:23–25, 153:2–10
218:2–25		109:4–13 119:24–120:2 120:5–10 153:11–13 153:15–20 153:23–154:18	403, I, NR	108:25, 109:14–20, 152:23–25, 153:2–10
219:2–6	602; S			
219:9–11	602; S			

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ATUL KAUSHIK (TEVA; CONTINUED)**November 5, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
219:14–17	403; 602; S; A&A			
219:20–25	I; 403; 602; S; A&A			
220:4–18		220:19–221:3	403, I	221:4–12
221:13–25	I			
222:2–3	I			
222:8–11	702/703			
222:14–16	701; 702/703			
223:8–20		109:4–13 119:24–120:2 120:5–10 153:11–13 153:15–20 153:23–154:18	403, I, NR	108:25, 109:14–20, 152:23–25, 153:2–10
223:23–25	I	109:4–13 119:24–120:2 120:5–10	403, I, NR	108:25, 109:14–20, 152:23–25, 153:2–10

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ATUL KAUSHIK (TEVA; CONTINUED)**November 5, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		153:11-13 153:15-20 153:23-154:18		
224:2-8	I	109:4-13 119:24-120:2 120:5-10 153:11-13 153:15-20 153:23-154:18	403, I, NR	108:25, 109:14-20, 152:23-25, 153:2-10
224:19-25	I	109:4-13 119:24-120:2 120:5-10 153:11-13 153:15-20 153:23-154:18	403, I, NR	108:25, 109:14-20, 152:23-25, 153:2-10
225:2-12	I, 602; 403	109:4-13 119:24-120:2	403, I, NR	108:25, 109:14-20, 152:23-25, 153:2-10

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Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		120:5–10 153:11–13 153:15–20 153:23–154:18		
225:15–25	I; 602	109:4–13 119:24–120:2 120:5–10 153:11–13 153:15–20 153:23–154:18 226:16–24	403, I, NR	108:25, 109:14–20, 152:23–25, 153:2–10
226:2–15	I; 602; S	226:16–24	403, I	
226:25	I	226:16–24	403, I	
227:2–25		226:16–24	403, I	
228:2–25	I; 701	153:11–13 153:15–20 153:23–154:18	403, I, NR	152:23–25, 153:2–10, 155:20–25

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		226:16–24 231:18–21 231:24–232:14 235:15–236:13		
229:2–10	I	226:16–24 229:11–12 229:14–15 229:19–20 231:18–21 231:24–232:14 235:15–236:13	403, I, NR	
229:25	I			
230:2–25	I; 702/703	153:11–13 153:15–20 153:23–154:18 226:16–24 229:11–12	403, I, NR	152:23–25, 153:2–10, 155:20–25

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		229:14–15 229:19–20 231:18–21 231:24–232:14 235:15–236:13		
231:2–12	I; 702/703	153:11–13 153:15–20 153:23–154:18 226:16–24 229:11–12 229:14–15 229:19–20 231:18–21 231:24–232:14 235:15–236:13	403, I, NR	152:23–25, 153:2–10, 155:20–25
232:15–25	I	226:16–24 229:11–12	403, I, NR	

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		229:14–15 229:19–20 231:18–21 231:24–232:14 235:15–236:13		
233:2–13	I; 702/703	226:16–24 229:11–12 229:14–15 229:19–20 231:18–21 231:24–232:14 235:15–236:13	403, I, NR	
233:22–25	I; 702/703; E	235:15–236:13	403, I	
234:2	I; 702/703; E			
234:5–8	I; 702/703; E	234:9 235:15–236:13	403, I, NR	
234:23–25	701; 702/703; E	235:15–236:13	403, I	

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Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
235:4–14	701; NQP; 702/703; E; 602; F; S	235:15–236:13	403, I	
236:25	I			
237:2–25	I; E	153:11–13 153:15–20 153:23–154:18 226:16–24 229:11–12 229:14–15 229:19–20 231:18–21 231:24–232:14 235:15–236:13 238:3–5 238:8–13	403, I, NR	152:23–25, 153:2–10, 155:20–25, 238:14–20
238:21–25	I; 702/703; E	153:11–13 153:15–20	403, I, NR	152:23–25, 153:2–10, 155:20–25, 238:14–

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		153:23–154:18 226:16–24 229:11–12 229:14–15 229:19–20 231:18–21 231:24–232:14 235:15–236:13 238:3–5 238:8–13		20
239:2–25	I; 702/703; E	153:11–13 153:15–20 153:23–154:18 226:16–24 229:11–12 229:14–15 229:19–20	403, I, NR	152:23–25, 153:2–10, 155:20–25, 238:14–20, 241:5–6, 241:9–13

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ATUL KAUSHIK (TEVA; CONTINUED)**November 5, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		231:18–21 231:24–232:14 235:15–236:13 238:3–5 238:8–13 241:14–16 242:9–10 242:13 243:13–16 243:19–21		
240:2–25	I; 701; 702/703; E	109:4–13 119:24–120:2 120:5–10 153:11–13 153:15–20 153:23–154:18 241:14–16	403, I, NR	108:25, 109:14–20, 152:23–25, 153:2–10, 241:5–6, 241:9–13

Plaintiff's Objection Key

403: Prejudicial, confusing, and/or waste of time
602: Lack of foundation
701: Opinion testimony by lay witness
Colloquy: Attorney colloquy or objection
NR: Not related
I: Incomplete

Defendants' Objection Key

403: Prejudicial
V: Vague and ambiguous
AF: Assuming facts not in evidence
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ATUL KAUSHIK (TEVA; CONTINUED)**November 5, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		242:9–10 242:13 243:13–16 243:19–21		
241:2–4	701; 702/703; E	241:14–16 242:9–10 242:13 243:13–16 243:19–21	403, I, NR	241:5–6, 241:9–13
241:18–20	602; S	241:14–16 242:9–10 242:13 243:13–16 243:19–21	403, I, NR	241:5–6, 241:9–13
241:23–25		241:14–16 242:9–10 242:13	403, I, NR	241:5–6, 241:9–13

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ATUL KAUSHIK (TEVA; CONTINUED)**November 5, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		243:13–16 243:19–21		
242:2–4	602; S	109:4–13 119:24–120:2 120:5–10 153:11–13 153:15–20 153:23–154:18 241:14–16 242:9–10 242:13 243:13–16 243:19–21	403, I, NR	108:25, 109:14–20, 152:23–25, 153:2–10, 241:5–6, 241:9–13
242:7–8	602; S	109:4–13 119:24–120:2 120:5–10 153:11–13	403, I, NR	108:25, 109:14–20, 152:23–25, 153:2–10, 241:5–6, 241:9–13

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ATUL KAUSHIK (TEVA; CONTINUED)**November 5, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		153:15–20 153:23–154:18 241:14–16 242:9–10 242:13 243:13–16 243:19–21		
243:23–25	NQP; 602; F; S	244:6–11	403, I	
244:12–25	I; 602; F; S	244:6–11	403, I	
245:2–24	602; F; S	244:6–11 245:25–246:12	403, I	
246:13–15	NQP, 602, F; S	246:16–18	403, I	
246:19–25	I; 602; F; S	246:16–18 249:12–250:2	403, I 403, I	250:10–22, 250:25, 251:2–3
247:2	I; 602; F; S	246:16–18 249:12–250:2	403, I, NR	250:10–22, 250:25, 251:2–3
247:9–25	I; 702/703; 701; 602;	246:16–18	403, I, NR	248:22–24, 250:10–

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ATUL KAUSHIK (TEVA; CONTINUED)**November 5, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
	F; S	248:11–21 249:12–250:2		22, 250:25, 251:2–3
248:2–6	I; 702/703; 701; 602; F; S	246:16–18 248:7–21 249:12–250:2	403, I, NR	248:22–24, 250:10–22, 250:25, 251:2–3
251:5–7	NQP; 602; F; S	251:8–10	403, I	
251:11–25	402; NR; 602; F; S; 701; 702/703; E	251:8–10	403, I	
252:2–6	402; NR; 602; F; S; 701; 702/703; E			
252:8–25	I; 602	253:7–13	403, I	
253:2–4	I; NQP; 602; F; S	253:7–13	403, I	
253:14–25	602; F; S	253:7–13	403, I	
254:2–25	602; 701; I; F; S	253:7–13	403, I, NR	
255:2–4	I; 701; 602; F; S	253:7–13	403, I, NR	
256:11–14	602; F; S; NQP			

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ATUL KAUSHIK (TEVA; CONTINUED)**November 5, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
257:5–25	602; F; S	258:18–260:6		
258:2–17	802	258:18–260:6		
260:8–10	602; F; S; NQP	260:11–13		
261:2–4	602; F; S; NQP	261:5–9		
261:10–25	I; 602; F; S	261:5–9		
262:2–25	I; 802; 701; 602; F; S	261:5–9		
263:2–13	402; 602; F; S	109:4–13 119:24–120:2 120:5–10 153:11–13 153:15–20 153:23–154:18 261:5–9 263:14–21	403, I, NR	108:25, 109:14–20, 152:23–25, 153:2–10
264:2–10	402; 602; F; S	261:5–9	403, I, NR	
264:14–25	402; 602; F; S	261:5–9	403, I, NR	

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ATUL KAUSHIK (TEVA; CONTINUED)**November 5, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
265:2–10	402; 602; F; S	261:5–9; 265:11–13	403, I, NR	
265:15–25	I			
266:2–25	402; 403; I	267:2–19	403, I	
268:4–5	I; 602; F; S			
268:12–23	403; 602; F; S; V			
268:25	403; 602; F; S; V			
269:2–4	403; 602; F; S; V			
269:17–19	602; F; S; V; NQP	269:20–24	403, I	
269:25	I; 602; F; S; V	269:20–24	403, I	
270:2–14	I; 602; F; S; V	269:20–24	403, I	
270:17–25	I; 602; F; S; V			
271:2–9	I; 602; F; S; V			
273:23–25	I; 602; F; S; V	269:20–24	403, I, NR	
274:2–25	402; 403; 602; F; S; V	269:20–24	403, I, NR	
275:2–16	I; 402; 602; F; S; V	269:20–24	403, I, NR	

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VATSAL SHAH (TEVA)
December 3, 2019 Deposition

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
6:2-11		124:25-125:3	403, I, NR	
9:16-25	I	10:4-6 10:9-11 124:25-125:14	403, I, NR	
10:2-3	I	10:4-6 10:9-11 124:25-125:14	403, I, NR	
10:12-25	I	10:4-6 10:9-11 124:25-125:14	403, I, NR	
11:2-13	I	10:4-6 10:9-11 124:25-125:14	403, I, NR	
13:12-21		14:9-15	403, I, NR	

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Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		124:25–125:3		
14:21–25	I	124:25–125:3	403, I, NR	
15:2–9	I	124:25–125:3	403, I, NR	
16:23–25	I, V, R, 403	10:4–6 10:9–11 124:25–125:3	403, I, NR 403, I	
17:2–25	I, V, R, 403, MIS, HYP, S	10:4–6 10:9–11 124:25–125:3	403, I, NR	
18:2–25	I, V	124:25–125:3	403, I, NR	
19:2–3	I			
19:7–11		124:25–125:3	403, I, NR	
19:22–25	MIS, S, R, 403, I	10:4–6 10:9–11 20:21–24 124:25–125:3	403, I, NR	

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VATSAL SHAH (TEVA; CONTINUED)
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Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
20:2–14	I, R, 403, S, 701, 702/703, F	10:4–6 10:9–11 20:21–24 124:25–125:3	403, I, NR	
21:8–25	MIS, R, 403, I	10:4–6 10:9–11 124:25–125:3	403, I, NR	
22:2–25	AF, V, I, R, 403	10:4–6 10:9–11 124:25–125:3	403, I, NR	
23:2–13	I	10:4–6 10:9–11 124:25–125:3	403, I, NR	
24:13–25	I	10:4–6 10:9–11 23:14–23 124:25–125:3	403, I, NR	

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25:2–25	I	10:4–6 10:9–11 23:14–23 124:25–125:3	403, I, NR	
26:2–24	MIS, I	10:4–6 10:9–11 23:14–23 124:25–125:3	403, I, NR	
30:10–23				
43:9–25	I	10:4–6 10:9–11 124:25–125:3	403, I, NR	
44:2–5	I	10:4–6 10:9–11 124:25–125:3	403, I, NR	
44:13–25	I	10:4–6	403, I, NR	

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Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		10:9–11 23:14–23 124:25–125:3		
45:2–25	I, V, NQP	10:4–6 10:9–11 23:14–23 124:25–125:3	403, I, NR	
46:2–25	I, V	10:4–6 10:9–11 23:14–23 124:25–125:3	403, I, NR	
47:2–25	I, F	10:4–6 10:9–11 23:14–23 124:25–125:3	403, I, NR	
48:2–3	I	10:4–6 10:9–11	403, I, NR	

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		23:14-23 48:4-11 124:25-125:3		
48:15-25	I	10:4-6 10:9-11 23:14-23 124:25-125:3	403, I, NR	
49:2-25	F, S, I	10:4-6 10:9-11 23:14-23 124:25-125:3	403, I, NR	
50:11-25	F, I	10:4-6 10:9-11 23:14-23 124:25-125:3	403, I, NR	
51:2-25	MIS, I	10:4-6 10:9-11	403, I, NR	

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		23:14-23 52:22-53:13 124:25-125:3		
52:2-21	I, A&A, F, S, V	10:4-6 10:9-11 23:14-23 52:22-53:13 124:25-125:3	403, I, NR	
53:17-25	I	10:4-6 10:9-11 23:14-23 52:22-53:13 54:12-14 124:25-125:3	403, I, NR	
54:2-11	I	10:4-6 10:9-11 23:14-23	403, I, NR	

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		52:22–53:13 54:12–14 124:25–125:3		
54:15–25	I	10:4–6 10:9–11 23:14–23 124:25–125:3	403, I, NR	
55:2–25	I, R, 403, F	10:4–6 10:9–11 23:14–23 124:25–125:3	403, I, NR	
56:2–13	I	10:4–6 10:9–11 23:14–23 56:14–28 124:25–125:3	403, I, NR	
57:24–25	I			

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58:2-12	V, F, I	10:4-6 10:9-11 23:14-23 124:25-125:3	403, I, NR	
58:23-25	I	10:4-6 10:9-11 23:14-23 124:25-125:3	403, I, NR	
59:2-25	I	10:4-6 10:9-11 23:14-23 124:25-125:3	403, I, NR	
60:2-25	I	10:4-6 10:9-11 23:14-23 124:25-125:3	403, I, NR	
61:2-24	V, F, I	10:4-6	403, I, NR	

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VATSAL SHAH (TEVA; CONTINUED)**December 3, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		10:9-11 23:14-23 124:25-125:3		
62:7-21	V, F, HYP, S	10:4-6 10:9-11 23:14-23 62:22-63:8 63:11-16 124:25-125:3	403, I, NR	
63:17-25		10:4-6 10:9-11 23:14-23 62:22-63:8 63:11-16 124:25-125:3	403, I, NR	
64:2-25	MIS, HYP, S	10:4-6 10:9-11	403, I, NR	

Plaintiff's Objection Key

403: Prejudicial, confusing, and/or waste of time
602: Lack of foundation
701: Opinion testimony by lay witness
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NR: Not related
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Defendants' Objection Key

403: Prejudicial
V: Vague and ambiguous
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VATSAL SHAH (TEVA; CONTINUED)
December 3, 2019 Deposition

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		23:14–23 124:25–125:3		
65:2–25	V, S, HYP, F, H	10:4–6 10:9–11 23:14–23 124:25–125:3	403, I, NR	
66:2–24	NS, V, R, 403, MIS, F, S, I	10:4–6 10:9–11 23:14–23 62:22–63:8 63:11–16 124:25–125:3	403, I, NR	
67:3–25	I	10:4–6 10:9–11 23:14–23 62:22–63:8 63:11–16	403, I, NR	

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VATSAL SHAH (TEVA; CONTINUED)**December 3, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		124:25–125:3		
68:2–25	NS, V, MIS, F	10:4–6 10:9–11 23:14–23 62:22–63:8 63:11–16 124:25–125:3	403, I, NR	
69:2–25	V, F, I	10:4–6 10:9–11 23:14–23 62:22–63:8 63:11–16 124:25–125:3	403, I, NR	
70:2–25	I	10:4–6 10:9–11 23:14–23 62:22–63:8	403, I, NR	

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December 3, 2019 Deposition

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		63:11–16 124:25–125:3		
71:2–9		10:4–6 10:9–11 23:14–23 124:25–125:3	403, I, NR	
71:13–25		10:4–6 10:9–11 23:14–23 124:25–125:3	403, I, NR	
72:2–17		10:4–6 10:9–11 23:14–23 124:25–125:3	403, I, NR	
73:14–25	I	10:4–6 10:9–11 23:14–23	403, I, NR	

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VATSAL SHAH (TEVA; CONTINUED)
December 3, 2019 Deposition

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		124:25–125:3		
74:2–9	I	10:4–6 10:9–11 23:14–23 124:25–125:3	403, I, NR	
74:16–25	F, I	10:4–6 10:9–11 23:14–23 124:25–125:3	403, I, NR	
75:2–6	F, I	10:4–6 10:9–11 23:14–23 124:25–125:3	403, I, NR	
75:12–25	F	10:4–6 10:9–11 23:14–23 124:25–125:3	403, I, NR	

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VATSAL SHAH (TEVA; CONTINUED)
December 3, 2019 Deposition

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76:2–25	MIS, I	10:4–6 10:9–11 23:14–23 124:25–125:3	403, I, NR	
77:2–25	I	10:4–6 10:9–11 23:14–23 124:25–125:3	403, I, NR	
78:2–25	R, 403, I, F	10:4–6 10:9–11 23:14–23 124:25–125:3	403, I, NR	
79:2–25	F, I	10:4–6 10:9–11 23:14–23 124:25–125:3	403, I, NR	
80:2–25	F, I	10:4–6	403, I, NR	

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VATSAL SHAH (TEVA; CONTINUED)
December 3, 2019 Deposition

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		10:9–11 23:14–23 124:25–125:3		
81:2–22	V, S, HYP, F, E, 702/703, I	10:4–6 10:9–11 23:14–23 124:25–125:3	403, I, NR	
81:25	I	10:4–6 10:9–11 23:14–23 124:25–125:3	403, I, NR	
82:2–25	MIS, V, I	10:4–6 10:9–11 23:14–23 124:25–125:3	403, I, NR	
83:2–25	F, I	10:4–6 10:9–11	403, I, NR	

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VATSAL SHAH (TEVA; CONTINUED)**December 3, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		23:14-23 124:25-125:3		
84:2-25	I	10:4-6 10:9-11 23:14-23 124:25-125:3	403, I, NR	
85:2-25	I	10:4-6 10:9-11 23:14-23 124:25-125:3	403, I, NR	
86:2-22	F, E, I	10:4-6 10:9-11 23:14-23 124:25-125:3	403, I, NR	
87:2-25	R, 403, I, E, MIS, F	10:4-6 10:9-11 23:14-23	403, I, NR	

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VATSAL SHAH (TEVA; CONTINUED)
December 3, 2019 Deposition

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
		124:25–125:3		
88:2–3	MIS, I, NQP	10:4–6 10:9–11 23:14–23 124:25–125:3	403, I, NR	
88:6–25	V, F, S, E, I	10:4–6 10:9–11 23:14–23 124:25–125:3	403, I, NR	
89:2–8	V, F, S, E, I	10:4–6 10:9–11 23:14–23 124:25–125:3	403, I, NR	
89:25	I			
90:2–25	I	23:14–23 124:25–125:3	403, I, NR	

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VATSAL SHAH (TEVA; CONTINUED)
December 3, 2019 Deposition

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
91:2-25	I	23:14-23 124:25-125:3	403, I, NR	
92:2-25	MIS, I	124:25-125:3	403, I, NR	
93:2-25	S, F, R, 403, V, I			
94:2-25	MIS, I			
95:2-25	F, V, I			
96:2-25	I			
97:2-25	F, I			
98:2-25	R, 403, I			
99:2-25	V, I			
100:2-25	MIS, I			
101:2-25	I			
102:2-15	F, I			
102:24-25				
103:2-25	I			

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VATSAL SHAH (TEVA; CONTINUED)
December 3, 2019 Deposition

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
104:2–25	V, I			
105:2–25	V, I			
106:2–7	I			
106:17–25	F, I			
107:2–11	S, I, F			
107:14–19	S, I			
108:3–8	F, I			
108:13–25	I			
109:7–25	I, MIS			
110:5–11	MIS, F, I			
110:14–19	MIS, F, I			
110:22–25	I			
111:2–19	I	111:20–22	403, I	
111:23–25	I			

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VATSAL SHAH (TEVA; CONTINUED)
December 3, 2019 Deposition

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
112:2-3	S, I, F			
112:6-19	I	112:20		
112:25	I			
113:2-9	I	113:10-21	403, I	
113:22-25	I			
114:2-21	S, I			
114:24-25	I			
115:2-6				
115:13-25	AF, I			
116:2-3	AF, I			
116:6-8	AF, S, I			
116:10	AF, S, I			
116:17-19	S, HYP, V, F, I			
116:22-25	I			
117:2-25	S, I			

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December 3, 2019 Deposition

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
118:2–25	I			
119:2–8	F, I			
125:20–25	A&A, I	124:25–125:3	403, I	
126:2–25	I	124:25–125:3	403, I	
127:2–25	R, 403	129:22–24 130:3–6	403, I, NR	
128:2–25	R, 403	129:22–24 130:3–6	403, I, NR	
129:2–4		129:5–8 129:22–24 130:3–6	403, I, NR	
129:9–21		129:5–8 129:22–24 130:3–6	403, I, NR	
130:7–25	V, F, S, I, HYP	129:22–24 130:3–6	403, I	

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131:2–25	V, S, F, HYP, I			
132:2–17	V, S, F, HYP, I			
133:16–21		133:22–25 134:2–5 134:8–10	403, I, NR	
134:11–23		133:22–25 134:2–5 134:8–10	403, I, NR	
135:6–13	MIS, H, I	133:22–25 134:2–5 134:8–10	403, I, NR	
135:17–25	A&A, I	133:22–25 134:2–5 134:8–10	403, I, NR	
136:2	A&A, I	133:22–25	403, I, NR	

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		134:2-5 134:8-10		
136:5-14	I	133:22-25 134:2-5 134:8-10	403, I, NR	
137:10-20	H	133:22-25 134:2-5 134:8-10	403, I, NR	
138:7-25	I	133:22-25 134:2-5 134:8-10	403, I, NR	
139:2-21	MIS, H, I			
139:24-25	I			
140:2-12	MIS, I			
140:15-22	A&A, I			
140:25	I			

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VATSAL SHAH (TEVA; CONTINUED)
December 3, 2019 Deposition

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
141:2–4	I, E			
141:6–20	OBJ, AF, F, I, R			
141:23–25	F, I, R			
142:2–14	A&A, I, R			

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MARTIN K. EHLERT (APOTEX)
December 10, 2019 Deposition

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
5:21–10:2		23:14–18		
10:6–19				
12:18–15:12				
16:14–19:10				
19:17–20:10				
30:20–21				
31:2–5				
31:11–18				
31:21–32:5		32:8–12		
32:15–19				
39:22–41:16				
42:6–12				
42:17–43:14				

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MARTIN K. EHLERT (APOTEX; CONTINUED)**December 10, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
43:16–47:9				
47:14–48:6				
48:8–51:1				
51:6–53:8				
53:15–55:13				
56:3–7				
56:14–60:15				
60:21–68:1				
68:3–79:7				
79:16–84:4				
84:6–22				
85:3–11				
86:20–87:15				
95:8–98:8				
106:7–10				

Plaintiff's Objection Key

403: Prejudicial, confusing, and/or waste of time
602: Lack of foundation
701: Opinion testimony by lay witness
Colloquy: Attorney colloquy or objection
NR: Not related
I: Incomplete

Defendants' Objection Key

403: Prejudicial
V: Vague and ambiguous
AF: Assuming facts not in evidence
E or 701 or 702/703: Calls for expert opinion, improper testimony of a lay witness
F or 602: Lacks foundation
H or 802: Hearsay

HYP: Improper hypothetical
I: Incomplete
MIS: Mischaracterizes evidence/testimony or is misleading
OBJ: Includes attorney objections
R or 402 or NR: Relevance
S: Calls for speculation

C: Compound
Scope: Outside the scope of 30(b)(6) designation
NQP or MA: No question posed
NA: No answer
A&A: Asked and answered
NS: Nonsensical

MARTIN K. EHLERT (APOTEX; CONTINUED)**December 10, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
106:14–107:1				
111:5–9	402	111:10	Colloquy	
111:11–15	402	111:16	Colloquy	
111:17–21	402	111:22	Colloquy	
112:1–20	402	111:21–22	Colloquy, I	
113:1–7				
113:11–114:6				
114:9				
114:20–21				
115:1–2				
115:4				
115:13–14				
115:16–116:16				
116:18				
116:20–119:17				

Plaintiff's Objection Key

403: Prejudicial, confusing, and/or waste of time
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701: Opinion testimony by lay witness
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NR: Not related
I: Incomplete

Defendants' Objection Key

403: Prejudicial
V: Vague and ambiguous
AF: Assuming facts not in evidence
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MARTIN K. EHLERT (APOTEX; CONTINUED)**December 10, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
119:21–122:10				
122:11–124:6				
124:20–125:11				
125:18–126:9		126:10–18	403, I	
126:19–127:18				
128:2–14				
128:20–130:8				
135:2–136:20				
137:1–139:8				
139:16–19				
140:6–7				
140:9–143:9				
143:20–145:22				
146:11–149:20				
149:22–150:5		150:6–152:16	403, 701	

Plaintiff's Objection Key

403: Prejudicial, confusing, and/or waste of time
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701: Opinion testimony by lay witness
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Defendants' Objection Key

403: Prejudicial
V: Vague and ambiguous
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MARTIN K. EHLERT (APOTEX; CONTINUED)**December 10, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
152:17–155:17				
155:20–157:6				
157:9–12				
157:15–158:20				
159:1–161:9				
161:12–163:13				
164:1–6				
164:10–166:22				
167:20–169:7				
169:20–170:1				
170:5–10				
170:13–18				
170:21–178:12				
179:1–6				
179:8–18				

Plaintiff's Objection Key

403: Prejudicial, confusing, and/or waste of time
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701: Opinion testimony by lay witness
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V: Vague and ambiguous
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MARTIN K. EHLERT (APOTEX; CONTINUED)**December 10, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
179:20–186:17				
187:10–189:11				
189:13–190:11				
191:8–195:21				
196:7–198:8				
198:18–200:21				
202:11–204:21				
205:1–207:2				
207:5–19				
207:22–208:4				
208:6–209:6				
209:9–21				
210:2–222:20				
223:1–13				
223:15–225:9				

Plaintiff's Objection Key

403: Prejudicial, confusing, and/or waste of time
602: Lack of foundation
701: Opinion testimony by lay witness
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I: Incomplete

Defendants' Objection Key

403: Prejudicial
V: Vague and ambiguous
AF: Assuming facts not in evidence
E or 701 or 702/703: Calls for expert opinion, improper testimony of a lay witness
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MARTIN K. EHLERT (APOTEX; CONTINUED)**December 10, 2019 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
225:12–226:11				
227:2–228:10				
228:12–15				
228:19–229:7				
229:13–230:13				
230:18–231:14				
231:19–232:5		232:6–16	Colloquy, 403	

Plaintiff's Objection Key

403: Prejudicial, confusing, and/or waste of time
602: Lack of foundation
701: Opinion testimony by lay witness
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NR: Not related
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Defendants' Objection Key

403: Prejudicial
V: Vague and ambiguous
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E or 701 or 702/703: Calls for expert opinion, improper testimony of a lay witness
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MARTIN K. EHLERT (APOTEX)
December 10, 2020 Deposition

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
6:2-25				
7:2-5				
7:13-25				
8:2				
8:6-10				
11:8-11				
12:11-17				
14:3-6	402			
14:11-21	402			
14:22-25	402			
15:2-13				
15:16-25	402			
16:2-12	402			

Plaintiff's Objection Key

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701: Opinion testimony by lay witness
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Defendants' Objection Key

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MARTIN K. EHLERT (APOTEX; CONTINUED)**December 10, 2020 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
16:16–25	402			
17:2–6	402			
17:10–17	402			
17:10–17	402			
17:20–24	402			
18:3–8	402			
18:11–21	402			
18:24–25				
19:2–13	402			
19:16–25	402			
20:4–8	402			
20:10–13				
21:5–25				
22:2–3				
23:16–25				

Plaintiff's Objection Key

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Defendants' Objection Key

403: Prejudicial
V: Vague and ambiguous
AF: Assuming facts not in evidence
E or 701 or 702/703: Calls for expert opinion, improper testimony of a lay witness
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MARTIN K. EHLERT (APOTEX; CONTINUED)**December 10, 2020 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
24:2-3				
24:6-25				
25:2-25				
26:2-20				
28:2-14				
28:20-22				
29:14-25				
30:2-25				
31:2-10				
31:14-25				
32:2-25				
33:2-12				
33:14-25				
34:2-6				
34:16-25				

Plaintiff's Objection Key

403: Prejudicial, confusing, and/or waste of time
602: Lack of foundation
701: Opinion testimony by lay witness
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Defendants' Objection Key

403: Prejudicial
V: Vague and ambiguous
AF: Assuming facts not in evidence
E or 701 or 702/703: Calls for expert opinion, improper testimony of a lay witness
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MARTIN K. EHLERT (APOTEX; CONTINUED)**December 10, 2020 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
35:2-10				
35:12-25				
36:3-25				
37:2-25				
38:2-25				
39:2-11				
39:13-25				
40:2-17				
40:20-22				
40:24-25				
41:2-14				
43:6-13				
43:17-20				
44:6-13				
44:15-25				

Plaintiff's Objection Key

403: Prejudicial, confusing, and/or waste of time
602: Lack of foundation
701: Opinion testimony by lay witness
Colloquy: Attorney colloquy or objection
NR: Not related
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Defendants' Objection Key

403: Prejudicial
V: Vague and ambiguous
AF: Assuming facts not in evidence
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MARTIN K. EHLERT (APOTEX; CONTINUED)**December 10, 2020 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
45:3–15				
46:12–18				

Plaintiff's Objection Key

403: Prejudicial, confusing, and/or waste of time
602: Lack of foundation
701: Opinion testimony by lay witness
Colloquy: Attorney colloquy or objection
NR: Not related
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Defendants' Objection Key

403: Prejudicial
V: Vague and ambiguous
AF: Assuming facts not in evidence
E or 701 or 702/703: Calls for expert opinion, improper testimony of a lay witness
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H or 802: Hearsay

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BHUPESH SINGH (APOTEX)
January 8, 2020 Deposition

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
7:10–8:6				
8:10–16				
8:18–10:4				
12:10–14:22				
15:3–4				
15:6–18:22				
21:10–22:18				
23:1–17				
24:3–5				
24:8–11				
24:13–18				
25:15–16				
25:19				

Plaintiff's Objection Key

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602: Lack of foundation
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Defendants' Objection Key

403: Prejudicial
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BHUPESH SINGH (APOTEX; CONTINUED)**January 8, 2020 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
25:22–26:1				
26:5–8				
26:21–27:10				
28:6–19				
29:5–9				
29:14–15				
29:17–20				
29:22–30:1				
30:3–7				
31:1–10				
31:18–32:3				
32:5–8				
32:10–14				
32:16–19				
32:21				

Plaintiff's Objection Key

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Defendants' Objection Key

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BHUPESH SINGH (APOTEX; CONTINUED)**January 8, 2020 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
33:1-3				
33:12-18				
33:20-21				
34:1-2				
34:4-6				
34:12				
34:18-22				
35:13-37:20				
38:6-39:6				
39:8-10				
39:12-22				
40:17-18				
40:21				
41:2				
41:6-8				

Plaintiff's Objection Key

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Defendants' Objection Key

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BHUPESH SINGH (APOTEX; CONTINUED)**January 8, 2020 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
45:13–14				
45:21–46:1				
46:15–16				
46:18–20				
55:19–22				
56:8–12				
56:14–19				
57:1–4				
57:21–22				
58:2–8				
58:10–21				
59:1–2				
59:4–11				
59:13–20		59:22–61:7	NR	
61:20–62:1		61:8–18		

Plaintiff's Objection Key

403: Prejudicial, confusing, and/or waste of time
602: Lack of foundation
701: Opinion testimony by lay witness
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Defendants' Objection Key

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BHUPESH SINGH (APOTEX; CONTINUED)**January 8, 2020 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
63:5–15				
64:10–12				
64:14–17				
68:16–22				
69:10–12	403, 701	69:1–8		
69:15–18		69:1–8		
69:20–70:3				
70:5–7				
72:10–20				
73:15–75:7				
75:9–14				
76:6–77:20				
79:9–19				
80:12–81:15				
81:17–82:1				

Plaintiff's Objection Key

403: Prejudicial, confusing, and/or waste of time
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Defendants' Objection Key

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BHUPESH SINGH (APOTEX; CONTINUED)**January 8, 2020 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
82:3-5				
83:7-10				
83:13-84:2				
84:4-10				
84:14-19				
85:2-20				
87:8-9				
87:11-15				
87:17-88:12				
88:22-89:10				
90:18-19				
90:21				
91:1-2				
91:4-5				
91:7-9				

Plaintiff's Objection Key

403: Prejudicial, confusing, and/or waste of time
602: Lack of foundation
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Defendants' Objection Key

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BHUPESH SINGH (APOTEX; CONTINUED)**January 8, 2020 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
91:11-13				
91:15-17				
91:19-92:2				
94:1-17				
97:17-98:9				
98:12-13				
98:15-18				
98:20-21				
99:1-5				
99:14-17				
106:20-21				
107:2				
107:5				
107:8				
107:11				

Plaintiff's Objection Key

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Defendants' Objection Key

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BHUPESH SINGH (APOTEX; CONTINUED)**January 8, 2020 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
107:15–108:7				
108:15–19				
110:10–14	403			
110:17–22		104:17–105:18; 106:13–19	NR, Colloquy	
111:2–7				
111:10–17				
111:19–114:20				
116:3–117:6				
117:11–13		60:15–61:1	NR	
118:2–4				
118:7–8				
119:1–123:7				
123:10–124:4				
124:7–125:10				
125:12–13				

Plaintiff's Objection Key

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Defendants' Objection Key

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BHUPESH SINGH (APOTEX; CONTINUED)**January 8, 2020 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
125:15–126:20				
128:13–132:6				
132:10–17				
133:20–135:1				
137:5–6				
137:10–19				
140:11–142:7				
145:21–146:10				

Plaintiff's Objection Key

403: Prejudicial, confusing, and/or waste of time
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Defendants' Objection Key

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Scope: Outside the scope of 30(b)(6) designation
NQP or MA: No question posed
NA: No answer
A&A: Asked and answered
NS: Nonsensical

BHUPESH SINGH (APOTEX)
November 19, 2020 Deposition

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
5:17-21				
7:5-13				
7:18-22				
7:25				
8:2-25				
9:2-8				
9:13-14				
11:6-9				
11:13-21				
15:20-25				
16:2-4				
17:7-15				
17:22-25				

Plaintiff's Objection Key

403: Prejudicial, confusing, and/or waste of time
602: Lack of foundation
701: Opinion testimony by lay witness
Colloquy: Attorney colloquy or objection
NR: Not related
I: Incomplete

Defendants' Objection Key

403: Prejudicial
V: Vague and ambiguous
AF: Assuming facts not in evidence
E or 701 or 702/703: Calls for expert opinion, improper testimony of a lay witness
F or 602: Lacks foundation
H or 802: Hearsay

HYP: Improper hypothetical
I: Incomplete
MIS: Mischaracterizes evidence/ testimony or is misleading
OBJ: Includes attorney objections
R or 402 or NR: Relevance
S: Calls for speculation

C: Compound
Scope: Outside the scope of 30(b)(6) designation
NQP or MA: No question posed
NA: No answer
A&A: Asked and answered
NS: Nonsensical

BHUPESH SINGH (APOTEX; CONTINUED)**November 19, 2020 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
18:2-6				
18:15-21				
18:24-25				
19:2-20				
21:5-25				
22:2-6				
23:16-25				
24:2-3				
24:22-25				
25:2-8				
25:15				
27:24-25				
28:2				
28:5-10				
29:15-17				

Plaintiff's Objection Key

403: Prejudicial, confusing, and/or waste of time
602: Lack of foundation
701: Opinion testimony by lay witness
Colloquy: Attorney colloquy or objection
NR: Not related
I: Incomplete

Defendants' Objection Key

403: Prejudicial
V: Vague and ambiguous
AF: Assuming facts not in evidence
E or 701 or 702/703: Calls for expert opinion, improper testimony of a lay witness
F or 602: Lacks foundation
H or 802: Hearsay

HYP: Improper hypothetical
I: Incomplete
MIS: Mischaracterizes evidence/testimony or is misleading
OBJ: Includes attorney objections
R or 402 or NR: Relevance
S: Calls for speculation

C: Compound
Scope: Outside the scope of 30(b)(6) designation
NQP or MA: No question posed
NA: No answer
A&A: Asked and answered
NS: Nonsensical

BHUPESH SINGH (APOTEX; CONTINUED)**November 19, 2020 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
29:20–25				
30:2–5				

Plaintiff's Objection Key

403: Prejudicial, confusing, and/or waste of time
602: Lack of foundation
701: Opinion testimony by lay witness
Colloquy: Attorney colloquy or objection
NR: Not related
I: Incomplete

Defendants' Objection Key

403: Prejudicial
V: Vague and ambiguous
AF: Assuming facts not in evidence
E or 701 or 702/703: Calls for expert opinion, improper testimony of a lay witness
F or 602: Lacks foundation
H or 802: Hearsay

HYP: Improper hypothetical
I: Incomplete
MIS: Mischaracterizes evidence/testimony or is misleading
OBJ: Includes attorney objections
R or 402 or NR: Relevance
S: Calls for speculation

C: Compound
Scope: Outside the scope of 30(b)(6) designation
NQP or MA: No question posed
NA: No answer
A&A: Asked and answered
NS: Nonsensical

BHUPESH SINGH (APOTEX)**July 29, 2021 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
5:9–11				
5:15–25				
6:2–5				
6:19–22				
7:10–25				
10:17–21				
11:13–25				
12:2–6				
12:13–25				
13:2–19				
13:23–25				
14:2–13				
15:2–5				

Plaintiff's Objection Key

403: Prejudicial, confusing, and/or waste of time
602: Lack of foundation
701: Opinion testimony by lay witness
Colloquy: Attorney colloquy or objection
NR: Not related
I: Incomplete

Defendants' Objection Key

403: Prejudicial
V: Vague and ambiguous
AF: Assuming facts not in evidence
E or 701 or 702/703: Calls for expert opinion, improper testimony of a lay witness
F or 602: Lacks foundation
H or 802: Hearsay

HYP: Improper hypothetical
I: Incomplete
MIS: Mischaracterizes evidence/ testimony or is misleading
OBJ: Includes attorney objections
R or 402 or NR: Relevance
S: Calls for speculation

C: Compound
Scope: Outside the scope of 30(b)(6) designation
NQP or MA: No question posed
NA: No answer
A&A: Asked and answered
NS: Nonsensical

KONDAL REDDY BAIRY (MSN; CONTINUED)**July 30, 2021 Deposition**

Vanda Designations	Defendants' Objections	Defendants' Counter-Designations	Vanda Objections	Vanda Counter-Designations
15:10–24				
16:3–5				
21:21–24				
23:9–25				
24:2–13				
30:17–20				
31:11–19				
32:2–7				
33:14–17				
34:3–16				

Plaintiff's Objection Key

403: Prejudicial, confusing, and/or waste of time
602: Lack of foundation
701: Opinion testimony by lay witness
Colloquy: Attorney colloquy or objection
NR: Not related
I: Incomplete

Defendants' Objection Key

403: Prejudicial
V: Vague and ambiguous
AF: Assuming facts not in evidence
E or 701 or 702/703: Calls for expert opinion, improper testimony of a lay witness
F or 602: Lacks foundation
H or 802: Hearsay

HYP: Improper hypothetical
I: Incomplete
MIS: Mischaracterizes evidence/testimony or is misleading
OBJ: Includes attorney objections
R or 402 or NR: Relevance
S: Calls for speculation

C: Compound
Scope: Outside the scope of 30(b)(6) designation
NQP or MA: No question posed
NA: No answer
A&A: Asked and answered
NS: Nonsensical

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

VANDA PHARMACEUTICALS)	
INC.,)	
)	
Plaintiff,)	
)	C.A. No. 18-651-CFC
v.)	CONSOLIDATED
)	
TEVA PHARMACEUTICALS USA,)	
INC.,)	
)	
Defendant.)	

EXHIBIT 9 - DEFENDANTS' DEPOSITION DESIGNATIONS

Defendants provide the following case-in-chief deposition designations, which are based on the parties' pleadings, documentary and testimonial evidence, and on Defendants' current understanding of Plaintiff's claims and defenses and the Court's rulings to date. Defendants designate this testimony pursuant to Federal Rule of Civil Procedure 26(a)(3).

Defendants reserve the right to revise, amend, supplement, or modify their case-in-chief deposition designations based upon any pretrial rulings by the Court or to address any additional issues, arguments, evidence or other developments in the case, including edits to the draft pretrial order, any meet and confers or other negotiations between the parties, pending and anticipated motions, and similar developments. Defendants further reserve the right to supplement these designations

to rebut or otherwise address deposition designations, exhibits, or other facts identified by Plaintiff. All irrelevant and redundant material, including objections and colloquy of counsel will be eliminated from the deposition designations below when the designations are read to or played to the Court. Defendants further reserve the right to designate any portion of the deposition transcripts of Plaintiff's 30(b)(6) representatives, officers, or employees should they fail to be in attendance at trial in this matter. Defendants further reserve the right to later provide designations from any deposition for use in their rebuttal case and to use any portion of any deposition transcript, whether listed below or not, for purposes of impeachment.

Deponent: Marlene Dressman, PhD. (December 9, 2019)

Defendant's Designation	Plaintiff's Objections¹	Plaintiff's Counter-Designation	Defendant's Objections
12:12-12:14			
14:12-14:14			
17:2-17:10	I	17:11–19:16, 22:9–20, 23:7–15, 28:3–16, 28:21– 29:7	R, 403, IC
21:8-21:13	I	17:11–19:16, 22:9–20, 23:7–15, 28:3–16, 28:21– 29:7	R, 403, IC

¹ Vanda notes that some of Defendants' designations may pertain to patents, claims, and/or claim elements that will no longer be applicable to the final set of patent claims Vanda asserts at trial. Vanda therefore reserves the right to object to Defendants' attempt to use such deposition designations on the additional ground of lack of relevance.

Defendant's Designation	Plaintiff's Objections¹	Plaintiff's Counter-Designation	Defendant's Objections
24:5-25:3	I	17:11–19:16, 22:9–20, 23:7–15, 28:3–16, 28:21– 29:7	R, 403, IC
28:17-28:20	I	17:11–19:16, 22:9–20, 23:7–15, 28:3–16, 28:21– 29:7	R, 403, IC
33:8-33:20	I	33:21–34:14	
35:20-36:8	I	33:21–34:14	
36:20-36:22	I	33:21–34:14	
37:8-37:10			
37:16-39:19	I	296:14–297:4, 298:13–16, 298:18–299:5	F, R, 403, V ²
40:1-41:5	I	41:6–42:13, 296:14–297:4, 298:13–16, 298:18–299:5	F, R, 403, V
44:14-47:4	I	47:5–15, 296:14– 297:4, 298:13–16, 298:18–299:5	F, R, 403, V
48:1-49:12	I	47:5–15, 296:14– 297:4, 298:13–16, 298:18–299:5	F, R, 403, V
52:9-52:17	I	296:14–297:4, 298:13–16, 298:18–299:5	F, R, 403, V
53:5-53:19	I	296:14–297:4, 298:13–16, 298:18–299:50	F, R, 403, V

² To the extent Vanda ultimately offers and the Court ultimately admits any testimony from 296:12–299:12, Defendants counter-counter-designate the testimony at 299:15–300:1.

Defendant's Designation	Plaintiff's Objections¹	Plaintiff's Counter-Designation	Defendant's Objections
55:6-55:19	I	55:21-56:12, 296:14-297:4, 298:13-16, 298:18-299:5	F, R, 403, V
59:6-60:2	I	56:13-58:22, 296:14-297:4, 298:13-16, 298:18-299:5	F, R, 403, V
60:5-61:17	I	60:3-4, 296:14- 297:4, 298:13-16, 298:18-299:5	F, R, 403, V
62:16-64:5	I	296:14-297:4, 298:13-16, 298:18-299:5	F, R, 403, V
65:7-65:21	I	64:21-65:3, 296:14-297:4, 298:13-16, 298:18-299:5	F, R, 403, V
66:4-69:6	I	296:14-297:4, 298:13-16, 298:18-299:5	F, R, 403, V
70:1-70:2	I	296:14-297:4, 298:13-16, 298:18-299:5	F, R, 403, V, IC
70:7-70:14	I	70:15-71:2, 71:8- 16, 296:14-297:4, 298:13-16, 298:18-299:5	F, R, 403, V, IC
78:16-78:17			
78:20-79:8			
81:2-82:16	I	79:17-80:14, 82:17-19, 298:13- 16, 298:18-299:5	F, R, 403, V
82:20-83:10	I	83:11-10, 298:13- 16, 298:18-299:5	F, R, 403, V

Defendant's Designation	Plaintiff's Objections¹	Plaintiff's Counter-Designation	Defendant's Objections
84:11-85:12	I	83:11-10, 298:13-16, 298:18-299:5	F, R, 403, V
85:15-85:16			
85:22-86:4			
86:12-86:16			
88:1-88:4	I, 403	86:17-87:22, 89:16-91:13, 296:14-297:4, 298:13-16, 298:18-299:5	F, R, 403, V
88:7-89:10	I, 602, 701	86:17-87:22, 89:16-91:13, 296:14-297:4, 298:13-16, 298:18-299:5	F, R, 403, V
89:13-89:15	I, 602, 701	86:17-87:22, 89:16-91:13, 296:14-297:4, 298:13-16, 298:18-299:5	F, R, 403, V
92:2-93:5	I, 701	91:17-92:1, 93:6-1, 297:20-298:12	F, R, 403, V
94:2-95:4	I, 602, 701	93:6-1, 297:20-298:12	F, R, 403, V
95:8-95:13	I, 602, 701	94:15-22, 297:20-298:12	F, R, 403, V
95:17-95:21	I, 602, 701	94:15-22, 297:20-298:12	F, R, 403, V
96:1-96:17	I, 602, 701	94:15-22, 297:20-298:12	F, R, 403, V
96:19-96:20	I, 602, 701	94:15-22, 297:20-298:12	F, R, 403, V
97:1-97:2			
97:6-97:20			
98:21-99:15	I, 602	99:16-100:10	
112:20-112:21			

Defendant's Designation	Plaintiff's Objections¹	Plaintiff's Counter-Designation	Defendant's Objections
113:1-113:12			
113:16-115:6	I	296:14-297:4, 298:13-16, 298:18-299:5	F, R, 403, V, IC
117:16-117:18	I, 602	117:19-118:4	
124:9-124:13	I, 602	117:19-118:4	
124:21-125:11			
126:11-126:12			
126:15-127:3			
131:18-131:19			
131:22-132:6			
135:19-135:22	I, 602, 701	134:5-6, 134:8-9, 136:16-20, 137:17-21. 138:1-12, 138:14-139:7, 139:10-19, 140:4-16, 140:20-141:9, 141:12-142:8	R, 403, IC
136:2-136:15	I, 602, 701	134:5-6, 134:8-9, 136:16-20, 137:17-21. 138:1-12, 138:14-139:7, 139:10-19, 140:4-16, 140:20-141:9, 141:12-142:8	R, 403, IC
144:4-144:15			
150:8-150:13	I, 602	149:4-8, 149:10-150:7	R, 403
150:15	I, 602	149:4-8, 149:10-150:7	R, 403
153:18-153:19	I	156:7-12	
154:1-154:4	I	156:7-12	
154:7-154:15	I	156:7-12	
155:7-156:3	I	156:7-12	
157:22-158:8			
160:1-160:4	I, 602	159:18-22	R, F, I

Defendant's Designation	Plaintiff's Objections¹	Plaintiff's Counter-Designation	Defendant's Objections
160:6-161:1	I, 602	159:18-22	R, F, I
162:12-162:20	I	163:2-11	
164:18-165:13	I	163:2-11	
165:15-165:21	I	163:2-11	
172:13-172:14			
172:16-172:17			
172:22-173:13			
176:11-176:19	I	177:3-178:8, 179:3-180:3	
178:17-178:20	I	177:3-178:8, 179:3-180:3	
179:1-179:2	I	177:3-178:8, 179:3-180:3	
181:7-181:10	I, 602, 701	297:20-298:12	R, 403, IC
181:12-181:17	I, 602, 701	297:20-298:12	R, 403, IC
181:19	I, 602, 701	297:20-298:12	R, 403, IC
187:8-187:16	I	185:8-16, 185:18-22, 186:2-187:7	R, 403, IC
207:13-207:14			
207:20-207:21			
208:4-208:8			
209:13-210:6	I, 602	210:7-20, 297:20-298:12	R, 403, IC
214:9-214:21	I, 602	185:8-16, 185:18-22, 186:2-187:7, 210:7-20, 297:20-298:12	R, 403, IC
219:22-220:4			
220:9-222:16	I	296:14-297:10, 298:13-16, 298:18-299:5	V, F, R, 403, IC
223:16-224:1	I	222:17-223:15, 224:2-21, 296:14-297:10, 298:13-16, 298:18-299:5	V, F, R, 403, IC

Defendant's Designation	Plaintiff's Objections¹	Plaintiff's Counter-Designation	Defendant's Objections
225:17-226:17	I	224:2–21, 296:14–297:10, 298:13–16, 298:18–299:5	V, F, R, 403, IC
228:18-229:5	I, 403, 701	230:6–232:10, 296:14–297:10, 298:13–16, 298:18–299:5	V, F, R, 403, IC ³
229:7-229:19	I, 403, 701	230:6–232:10, 296:14–297:10, 298:13–16, 298:18–299:5	V, F, R, 403, IC
229:21-230:1	I, 403, 701	230:6–232:10, 296:14–297:10, 298:13–16, 298:18–299:5	V, F, R, 403, IC
230:3	I, 403, 701	230:6–232:10, 296:14–297:10, 298:13–16, 298:18–299:5	V, F, R, 403, IC
232:13-232:22	I, 403, 701	230:6–232:10, 296:14–297:10, 298:13–16, 298:18–299:5	V, F, R, 403, IC
233:11-233:12	I	296:14–297:10, 298:13–16, 298:18–299:5	V, F, R, 403, IC
234:6-234:14	I	296:14–297:10, 298:13–16, 298:18–299:5	V, F, R, 403, IC
235:2-235:6	I	235:17–236:9, 296:14–297:10,	V, F, R, 403, IC

³ To the extent Vanda ultimately offers and the Court ultimately admits the testimony at 230:6–232:10, Defendants counter-counter-designate the testimony at 232:11–12.

Defendant's Designation	Plaintiff's Objections¹	Plaintiff's Counter-Designation	Defendant's Objections
		298:13–16, 298:18–299:5,	
235:8-235:16	I	235:17–236:9, 296:14–297:10, 298:13–16, 298:18–299:5,	V, F, R, 403, IC
242:21-242:22			
243:5-243:6			
243:8-244:4			
244:8-244:9	I, 602	244:11–14	R, 403
244:15-244:21	I, 602	244:11–14	R, 403
245:4-245:21			
246:1-246:11	I, 602, 701	246:22–247:2, 247:4–14, 247:16– 18, 248:10–19, 250:4–5, 250:7–8, 252:2–4, 252:6–9, 252:11–12, 287:16–17, 287:19–22, 296:14–297:10, 298:13–16, 298:18–299:5	V, F, R, 403, IC
246:13-246:17	I, 602, 701	246:22–247:2, 247:4–14, 247:16– 18, 248:10–19, 250:4–5, 250:7–8, 252:2–4, 252:6–9, 252:11–12, 287:16–17, 287:19–22, 296:14–297:10, 298:13–16, 298:18–299:5	V, F, R, 403, IC
246:19-246:21	I, 602, 701	246:22–247:2, 247:4–14, 247:16–	V, F, R, 403, IC

Defendant's Designation	Plaintiff's Objections¹	Plaintiff's Counter-Designation	Defendant's Objections
		18, 248:10–19, 250:4–5, 250:7–8, 252:2–4, 252:6–9, 252:11–12, 287:16–17, 287:19–22, 296:14–297:10, 298:13–16, 298:18–299:5	
247:19-247:21	I, 602, 701	246:22–247:2, 247:4–14, 247:16–18, 248:10–19, 250:4–5, 250:7–8, 252:2–4, 252:6–9, 252:11–12, 287:16–17, 287:19–22, 296:14–297:10, 298:13–16, 298:18–299:5	V, F, R, 403, IC
248:1-248:4	I, 602, 701	246:22–247:2, 247:4–14, 247:16–18, 248:10–19, 250:4–5, 250:7–8, 252:2–4, 252:6–9, 252:11–12, 287:16–17, 287:19–22, 296:14–297:10, 298:13–16, 298:18–299:5	V, F, R, 403, IC
248:6	I, 602, 701	246:22–247:2, 247:4–14, 247:16–18, 248:10–19, 250:4–5, 250:7–8, 252:2–4, 252:6–9, 252:11–12,	V, F, R, 403, IC

Defendant's Designation	Plaintiff's Objections¹	Plaintiff's Counter-Designation	Defendant's Objections
		287:16–17, 287:19–22, 296:14–297:10, 298:13–16, 298:18–299:5	
249:18-249:21	I, 602, 701	246:22–247:2, 247:4–14, 247:16–18, 248:10–19, 250:4–5, 250:7–8, 252:2–4, 252:6–9, 252:11–12, 287:16–17, 287:19–22, 296:14–297:10, 298:13–16, 298:18–299:5	V, F, R, 403, IC
250:1-250:3	I, 602, 701	246:22–247:2, 247:4–14, 247:16–18, 248:10–19, 250:4–5, 250:7–8, 252:2–4, 252:6–9, 252:11–12, 287:16–17, 287:19–22, 296:14–297:10, 298:13–16, 298:18–299:5	V, F, R, 403, IC
250:9-250:11	I, 602, 701	246:22–247:2, 247:4–14, 247:16–18, 248:10–19, 250:4–5, 250:7–8, 252:2–4, 252:6–9, 252:11–12, 287:16–17, 287:19–22, 296:14–297:10,	V, F, R, 403, IC

Defendant's Designation	Plaintiff's Objections¹	Plaintiff's Counter-Designation	Defendant's Objections
		298:13–16, 298:18–299:5	
252:18-253:3	I, 701	298:13–16, 296:14–297:10, 298:18–299:5	V, F, R, 403, IC
258:10-258:13	I, 701	257:4–12, 257:14– 258:1, 258:3–9	
260:12-261:4	I	297:12–298:12, 299:6–10	R, 403
261:17-261:18	I, 701	262:7, 262:9– 263:3, 263:5– 264:1, 297:12– 298:12, 299:6–10	R, 403
261:20-262:6	I, 701	262:7, 262:9– 263:3, 263:5– 264:1, 297:12– 298:12, 299:6–10	R, 403
266:5-266:6	I	268:13–16, 268:18–269:18, 297:12–298:12, 299:6–10	R, 403, IC
266:8-266:15	I	268:13–16, 268:18–269:18, 297:12–298:12, 299:6–10	R, 403, IC
270:21-271:6	I	297:12–298:12, 299:6–10	R, 403, IC
271:17-271:20	I	297:12–298:12, 299:6–10	R, 403, IC
271:22-272:12	I	297:12–298:12, 299:6–10	R, 403, IC
272:20-272:22	I, 602, 701	297:12–298:12, 299:6–10	R, 403
273:2-273:4	I, 602, 701	297:12–298:12, 299:6–10	R, 403

Defendant's Designation	Plaintiff's Objections¹	Plaintiff's Counter-Designation	Defendant's Objections
273:6-273:7	I, 602, 701	297:12-298:12, 299:6-10	R, 403
273:9	I, 602, 701	297:12-298:12, 299:6-10	R, 403
274:12-274:14	I, 602, 701	297:12-298:12, 299:6-10	R, 403
275:1-275:3	I, 602, 701	297:12-298:12, 299:6-10	R, 403
275:5-275:6	I, 602, 701	275:7, 297:12-298:12, 299:6-10	R, 403, I
276:9-276:10	I, 602, 701	297:12-298:12, 299:6-10	R, 403, IC
276:12-276:17	I, 602, 701	297:12-298:12, 299:6-10	R, 403, IC
276:19-276:20	I, 602, 701	297:12-298:12, 299:6-10	R, 403, IC
278:15-278:21	I, 701	297:20-298:12	R, 403
279:1-279:4	I, 701	297:20-298:12	R, 403
279:6-279:10	I, 701	297:20-298:12	R, 403
279:14-280:2			
283:10-283:11			
283:14-284:2			
286:12-286:13			
286:20-287:7			
290:19-290:20			
290:22-291:10			
292:3-292:8	I, 602, 701	297:12-298:12, 299:6-10	R, 403
292:10-292:13	I, 602, 701	297:12-298:12, 299:6-10	R, 403
292:15-292:17	I, 602, 701	297:12-298:12, 299:6-10	R, 403
292:19-292:22	I, 602, 701	297:12-298:12, 299:6-10	R, 403
293:2	I, 602, 701	297:12-298:12, 299:6-10	R, 403

Deponent: Natalie M. Farris (December 3, 2019)

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
11:2-11:8			
16:11-16:20			
18:15-19:4	Colloquy	19:16-21:5	R; Improper counter-designation
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29:15-31:18	I, 602, 701	31:19-32:1	R; Improper counter-designation
32:2-33:21	Colloquy, I, 602, 701	33:22-35:20	R
35:21-36:10	I, 602, 701	36:11-37:8	R
37:22-38:4	402	38:8-39:4	R; Improper counter-designation
39:5-41:4	I, 602, 701		
41:16-42:2	I	42:3-10	
42:11-44:13	I, 602, 701	44:14-22	
45:1-46:12	I, 602, 701	46:13-48:7	
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50:3-50:13	I, 602, 701	50:14-51:16	
51:17-52:21	I, 602, 701		
53:14-54:1	I, 602, 701	54:2-19	R; Improper counter-designation
54:20-55:4	I, 602, 701	55:5-56:3	
56:4-56:15	I		
56:17-57:9	I		
61:22-62:12			

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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64:8-64:21	I, 602, 701	63:18-20, 64:1-7	
66:5-66:20	I, 602, 701		
67:2-67:9	I, 602, 701	67:10-18, 67:21-68:19, 68:20-72:4	
72:8-72:11	I, 602, 701		
72:15-73:21	I, 602, 701		
75:13-77:3	602, 701		
77:7-77:20	602, 701		
78:10-78:14	602, 701		
78:18-79:13	602, 701		
79:17-80:15	602, 701		
80:19-81:15	602, 701		
81:19-83:3	602, 701		
83:22-84:20	602, 701		
85:1	I		
85:5-85:7	I		
85:11-85:18	I	85:19-86:5	
86:9-96:12	602, 701		
97:10-98:9	602, 701		
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105:15-106:18	602, 701		
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109:2-109:14	602, 701		
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109:21-111:6	602, 701		
111:19-111:22	602, 701		
112:3-114:20	I, 602, 701	114:21-115:8, 116:8-19	

Deponent: John Joseph Feeney, III, M.D. (December 6, 2019)

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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11:1-11:3	402, 403		
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17:1-18:9			
29:17			
29:19-29:20			
33:1-33:2			
33:7-33:16	I, 602	43:21-44:2, 44:17-45:7	R, 403, IC
34:3-34:7	I	31:15-32:4, 43:21-44:2, 44:17-45:7	R, 403, IC
36:10-36:19	I, 602	34:12-35:12, 43:21-44:2, 44:17-45:7	R, 403, IC, OBJ
37:4-37:5	I, 602	43:21-44:2, 44:17-45:7	R, 403, IC
37:7-37:10	I, 602	43:21-44:2, 44:17-45:7	R, 403, IC
37:12-37:13	I, 602	43:21-44:2, 44:17-45:7	R, 403, IC
38:21-38:22	I, 602	43:21-44:2, 44:17-45:7	R, 403, IC
39:2-39:8	I, 602	43:21-44:2, 44:17-45:7	R, 403, IC
41:12-41:18	I, 602, 701	43:21-44:2, 44:17-45:7	R, 403, IC
41:20-42:4	I, 602	43:21-44:2, 44:17-45:7	R, 403, IC
42:7	I, 602	43:21-44:2, 44:17-45:7	R, 403, IC
46:10-46:22	I, 403, 602	43:21-44:2, 44:17-45:7	R, 403, IC

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
47:3	I, 403, 602	43:21–44:2, 44:17–45:7	R, 403, IC
49:14-49:19	I, 602, 701	43:21–44:2, 44:17–45:7, 48:21–49:13	R, 403, IC, OBJ
49:21-50:5	I, 602, 701	43:21–44:2, 44:17–45:7, 48:21–49:13	R, 403, IC, OBJ
50:7-50:14	I, 602, 701	43:21–44:2, 44:17–45:7, 48:21–49:13	R, 403, IC, OBJ
50:19	I, 602, 701	43:21–44:2, 44:17–45:7, 48:21–49:13	R, 403, IC, OBJ
52:1-52:3	I, 403, 602	43:21–44:2, 44:17–45:7	R, 403, IC
52:8-52:18	I, 403, 602	43:21–44:2, 44:17–45:7, 51:18–22	R, 403, IC
56:1-56:5	I, 403, 602	43:21–44:2, 44:17–45:7	R, 403, IC
56:8-56:19	I, 403, 602, 701	43:21–44:2, 44:17–45:7, 54:16–20, 55:11–19	R, 403, IC
56:22-57:4	I, 602, 701	43:21–44:2, 44:17–45:7, 54:16–20, 55:11–19	R, 403, IC
57:8-57:20	I, 602, 701	43:21–44:2, 44:17–45:7, 54:16–20, 55:11–19	R, 403, IC
57:22	I, 602, 701	43:21–44:2, 44:17–45:7, 54:16–20,	R, 403, IC

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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59:5	602, 701		
59:20-59:21			
60:5-60:13			
65:3-65:5			
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66:18-66:22	602, 701		
67:6-68:17	I, 602, 701	68:19–69:12	
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70:2-71:4	I, 602, 701	69:13–19	
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72:8-72:22			
74:7-74:12	I, 602, 701	73:11–18, 74:14–17, 74:20–21	R, 403
76:7-77:1	I, NS, NQP, NA		Typo corrected in original designation
77:4	I, 602, 701	80:3–5, 80:7–10	R, 403
77:7-77:10	I, 602, 701	80:3–5, 80:7–10	R, 403
77:13-77:14	I, 602, 701	80:3–5, 80:7–10	R, 403
78:5-78:8	I, 602, 701	80:3–5, 80:7–10	R, 403
78:10-78:15	I, 602, 701	80:3–5, 80:7–10	R, 403
82:8-82:9	I	83:2–13, 85:3–7	R, 403, IC
82:16-82:17	I	83:2–13, 85:3–7	R, 403, IC
84:5-84:8	I	83:2–13, 85:3–7	R, 403, IC
84:15-85:2	I	83:2–13, 85:3–7	R, 403, IC
85:17-85:21	I, 403, 602, 701	83:2–13, 85:3–7	R, 403
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89:7-90:6	I, 402	90:7–11	
90:22-91:1	I, 602	91:6–14	

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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93:1-93:3	I, 602, 701	91:6-14, 92:2-9, 92:12-14	
93:12-93:17	I, 602	93:9-11	
94:20-94:21	I, 602	95:5-7	
95:8-95:22	I, 602	95:5-7	
97:11-97:15	I, 602, 701	95:5-7, 96:6-11, 96:14-97:10	
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104:18-104:21	I, 403, 602, 701	101:4-8, 013:8-16, 103:18-104, 10, 104:14-17	NS, I
105:2-105:5	I, 403, 602, 701	101:4-8, 013:8-16, 103:18-104, 10, 104:14-17	NS, I
109:16-109:19	I, 602,701	106:6-10, 106:13-107:7, 107:10-108:9, 108:12-109:15	R, 403
109:22-110:4	I, 602,701	106:6-10, 106:13-107:7, 107:10-108:9, 108:12-109:15	R, 403
110:11-110:13	602,701		
110:15-111:3	602,701		
111:6-111:13	602,701		
113:4-113:8	I, 602,701	113:9-114:2	
114:3-114:4	I, 602,701	113:9-114:2	
114:6	I, 602,701	113:9-114:2	
114:22-115:12	I, 602, 701	114:7-14	

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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122:10-122:12	I, 403, 602, 701	93:9-11, 116:3-14, 116:17-117:17, 118:15-120:12, 120:14-122:3	R, 403
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125:17-126:21	602		
127:2-128:2	403, 602, 701		
128:5-129:11	403, 602, 701		
129:13-130:15	602, 701		
132:22-133:1	I, 602	133:19-134:9, 134:19-135:5, 135:8-16, 135:20-21	I
133:6-133:18	I, 602	133:19-134:9, 134:19-135:5, 135:8-16, 135:20-21	I
134:10-134:17	I, 602, 701	133:19-134:9, 134:19-135:5, 135:8-16, 135:20-21	I
136:2	602		
136:4-136:15	602, 402, 403		
137:7-137:9	602, 402, 403		
137:15	602, 402, 403		
138:3-138:4	I, 602	138:18-17	NS, I
138:9-138:14	I, 602	138:18-17	NS, I
138:18-138:19	I, 602	139:2-5	
139:6-139:14	602		

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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140:8-140:9	I, 403, 602	140:10-12, 140:15-17	
146:17-146:18	I, 602	146:4-16	R, 403
147:1-147:5	I, 602	146:4-16	R, 403
147:7-147:9	I, 602	146:4-16	R, 403
147:11-147:19	I, 602	146:4-16	R, 403
148:1-148:3			
148:7-148:9			
148:13-148:15			
148:19-148:21			
149:3-149:5			
149:10-149:16			
151:11-151:18	701		
152:2-152:5			
160:8-160:11	I, 602, 701	157:6-16, 177:6- 178:12, 178:13- 179:2, 192:3- 180:11	R, 403, NS, I
160:16-160:19	I, 602, 701	157:6-16, 177:6- 178:12, 178:13- 179:2, 192:3- 180:11	R, 403, NS, I
161:16-161:18	I, 602, 701	157:6-16, 177:6- 178:12, 178:13- 179:2, 192:3- 180:11	R, 403, NS, I
161:21-161:22	I, 602, 701	157:6-16, 177:6- 178:12, 178:13- 179:2, 192:3- 180:11	R, 403, NS, I
162:2-162:3	I, 602, 701	157:6-16, 177:6- 178:12, 178:13- 179:2, 192:3- 180:11	R, 403, NS, I

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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163:10-163:11	I, 602, 701	162:16-163:4, 177:6-178:12, 178:13-179:2, 192:3-180:11	R, 403, NS, I
164:1-164:5	I	177:6-178:12, 178:13-179:2, 192:3-180:11	R, 403, NS, I
164:14-164:16	I, 602, 701	164:10-13, 177:6-178:12, 178:13-179:2, 192:3-180:11	R, 403, NS, I
181:16-181:18	I, 402, 403	182:6-8	
181:21	I, 402, 403	182:6-8	
182:1-182:5	I, 402, 403	182:6-8	
183:10-183:11	I, 402, 403	182:6-8	
183:16-183:21	I, 402, 403	182:6-8	
185:19-185:22	I, 402, 403, 602	182:6-8	
186:2-186:4	I, 402, 403, 602	182:6-8	

Deponent: Louis Licamele, Ph.D. (December 13, 2019)

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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18:15-19:1	I	19:2-21:13, 22:4-24:15, 24:17-15,	R, IC

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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30:2-30:3			
30:8-30:17			
39:6-39:14	I	38:18–39:1, 39:3–4	IC
54:10-54:19	I	53:6–54:2, 54:4–8	IC
68:6-68:20	I, 701	66:13–15, 66:20–67:5, 67:7, 67:9–11, 68:21	S, F, E, R, IC
81:4-82:19			
87:14-87:22	I	88:10–89:12	IC
96:18-97:1			
100:9-100:10			
101:9-101:13	I, 602	101:14–18, 101:20–22	V, S
102:22-104:12	I, 602	101:14–18, 101:20–22	V, IC
112:16-113:4	I, 602	111:6–16, 111:18–21	
115:13-116:2	I, 602	111:6–16, 111:18–21, 117:2–4, 117:6–8	V, NQP, IC
116:5-116:21	I, 602	111:6–16, 111:18–21, 117:2–4, 117:6–8	V, NQP, IC
119:2-121:14	I, 602	123:3–16	R, IC
123:17-125:22	I	123:3–16	R, IC
135:17-135:18			
136:1-136:3			
136:10-137:22	I, 602	138:20–139:10, 143:6–7, 143:9–10, 143:12–18, 171:13–172:9, 172:11–15	IC, I, S, AF

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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141:6-142:15	I, 602	138:20-139:10, 139:19-140:5, 142:16, 143:6-7, 143:9-10, 143:12-18, 171:13-172:9, 172:11-15	IC, I, S, AF
150:15-151:7	I, 602	138:20-139:10, 139:19-140:5, 142:16, 143:6-7, 143:9-10, 143:12-18, 171:13-172:9, 172:11-15	IC, I, S, AF
158:7-160:16	I, Colloquy	157:5-13	R, I, NQP, IC
161:6-162:4	I	163:11-164:10, 164:12-15	IC, I, S
175:17-179:3	I, 602, 701, Colloquy	179:4-12, 179:14-20	IC, I
181:8-181:17			
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221:9-221:16			
221:21-222:5			
222:10-222:16			
222:21-223:5			
223:10-223:14			
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226:4-226:5			
228:6-228:8	I, 602	138:20-139:10, 139:19-140:5, 142:16, 143:6-7, 143:9-10, 143:12-	IC, I, S, AF

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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232:2-233:14	I, 602, Colloquy	138:20–139:10, 139:19–140:5, 142:16, 143:6–7, 143:9–10, 143:12–18, 171:13–172:9, 172:11–15	IC, I, S, AF
233:21-234:3			
234-7-235:4	602		
236:10-237:9	602		
239:5-240:3	I, 602, Colloquy	107:5–109:19, 126:21–128:11, 237:6–9, 255:14–257:14	R, IC, I, S, AF
241:20-243:2	I, 602	107:5–109:19, 126:21–128:11, 237:6–9, 255:14–257:14	R, IC, I, S, AF
243:11-245:14	I, 602	107:5–109:19, 126:21–128:11, 237:6–9, 255:14–257:14	R, IC, I, S, AF

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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248:21-250:4	I	252:9-254:18, 245:20-257:14	R, OBJ, NQP, I, IC
251:7-252:8	I	252:9-254:18, 245:20-257:14	R, OBJ, NQP, I, IC

Deponent: Ravi Pandrapragada, Ph.D. (December 11, 2019)

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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11:18-11:21	I		
12:11-12:20	I, 602, 701	12:21-13:1	I, V, 701
13:2-13:14	I, 602, 701	13:15-22	R, 701
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18:7-19:11	I, 602, 701	19:12-18, 19:20- 20:3	I, 701, IC
20:4-22:2	I, 602, 701		
22:10-23:9	602, 701		
24:2-25:5	NQP, I	25:20-26:19	R
27:7-27:8	I, 402	27:3-6, 27:9-11, 27:14-16, 28:1-7	R, IC
27:12-27:13	I, 402		
27:17-27:22	I, 402		
28:8-28:13	I, 602, 701	28:14-29:6	R, IC
29:7-30:16	I, 602, 701	31:5-32:6, 32:8- 33:8, 33:18-34:9	R, H, IC
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37:16-37:19	I, 602, 701	37:20-38:3	I, V, 701, R
38:4-38:22	I, 602, 701	39:2-22	I, 701, R, IC
40:1-40:11	I, 602, 701	40:12-22	701, R, IC
41:1-41:3	I, 602, 701	41:4-9	R, IC

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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42:8-43:15	I, 602, 701	43:16-44:7	R, IC, AF, S
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47:6-48:21	I, 602, 701	48:22-49:21	V, R, IC, AF, S
49:22-51:12	I, 602, 701		
51:15-51:18	I, 602, 701	51:20-52:4	V, S, H
52:8-52:13	I, 602, 701	52:14-53:14, 53:16-20	I, R, NQP, IC
54:10-54:15	I, 602, 701	54:16-55:15, 55:17-21, 56:1-13, 56:15-22	V, R, 701, IC, AF, S
57:1-57:4	I, 602, 701	57:5-13	V, R, 701, IC, AF, S
57:14-57:18	I, 602, 701		
57:20-58:7	I, 602, 701		
58:9-59:4	I, 602, 701	59:11, 59:14-17	I, V, 701, IC, NQP
60:2-60:20	I, 602, 701		
61:1-61:9	I, 602, 701		
61:11-62:1	I, 602, 701		
62:4-62:5	I, 602, 701		
62:11-63:13	I, 602, 701	63:14-19	I, R, 701
63:20-64:16	I, 602, 701	64:17-65:8	I, R, 701, H, IC, AF, S
65:12-66:21	I, 602, 701		
67:1-67:7	I, 602, 701		
67:10-68:7	I, 602, 701	68:8-70:13	I (needs at least 70:14-71:8), R, 701, H
70:20-71:20	I, 602, 701		
72:7-73:3	I, 602, 701	73:4-74:10	I, R, 701, H
74:11-75:7	I, 602, 701	75:8-20	R, 701, H
75:21-76:10	I, 602, 701	76:11-78:7	R, 701
78:8-78:17	I, 602, 701		

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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86:10-86:18	I, 602, 701	87:2-88:16	R, 701, IC, I
88:17-89:6	I, 602, 701		
93:14-95:2	I, 602, 701		
95:6-96:9	I, 602, 701	95:10-96:7	I, IC
96:16-96:20	I, 602, 701		
96:22-98:7	I, 602, 701		
98:9	I, 602, 701		
98:11-100:11	I, 602, 701	100:12-16	I, R, IC
101:4-101:6			
101:9-102:3	I, 602, 701		
102-11-102:13	I, 602, 701		
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103:4-103:10	I, 602, 701	103:13-17	I, R, IC
103:18-104:10	I, 602, 701	104:11-105:4, 108:14-109:10	I (needs at least 109:15-19), V, 403, 701, IC, AF, S
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Deponent: Deepak Phadke, Ph.D. (November 15, 2019)

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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35:13-36:6	I	31:19-33:1, 342:8-343:4, 343:7-8, 343:10-344:11,	

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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46:12-13			46:12-13 was unintentionally omitted from Def's dep des.
46:15-46:21	I	226:6-9, 226:22-227:14, 227:17-18, 266:21, 267:1-6, 267:8-9, 295:12-14, 295:17-22	

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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91:1	I	68:8-17, 68:22-69:2, 69:4-16, 70:14-15, 70:17-19, 71:4-9, 71:11-	

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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92:16-93:10	I	37:10-11, 52:10-12, 2:14-15, 57:2-	I (Testimony @ 193:-10 does not

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
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95:2-95:3	I		
95:6-95:12	I		
95:14-95:22	I		
96:9-96:15	I		
96:17-96:20	I		
96:22	I		
109:18-110:2	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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110:12-110:16	I	111:4-111:6	
110:18-110:19	I	111:4-111:6	
111:11-111:16	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11,	this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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111:19-112:8	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
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112:21-112:22	I		
113:2-113:11	I		
113:13	I		
113:15-114:3	I		
114:5-114:12	I		
115:12-115:13	I		
115:16-115:22	I		
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118:11-118:13	I		
125:20-126:8	I	134:3-5	
127:13-127:14	I	126:13-18, 129:11-12, 129:15-130:3, 130:18-20, 130:22-131:5, 131:8-11, 131:13-15, 131:17-19,	Please correct the typo 195-14 throughout.

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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127:19-127:22	I	126:13-18, 129:11-12, 129:15-130:3, 130:18-20, 130:22-131:5, 131:8-11, 131:13-15, 131:17-19, 132:1-14, 134:3-5, 195:8-11, 195-14-18	
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128:11-128:18	I	126:13-18, 129:11-12, 129:15-130:3, 130:18-20,	

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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134:14-134:22	I		
135:2-135:3	I		
135:5-135:21	I		
136:22-137:14	I		
137:16-138:4	I	68:8-17, 68:22-69:2, 69:4-16, 70:14-15, 70:17-19, 71:4-9, 71:11-19, 72:20-73:4, 73:7, 73:14-17, 73:19-74:6, 74:8-12, 87:2-11, 87:13-14, 87:19-88:11, 197:9, 197:11-15	
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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139:8-139:12	I		
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145:1-145:7	I, 402, 403, 602	140:22-141:4, 143:11-12, 143:15-144:11, 144:14-144:15	
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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165:12-165:17	I		
165:21-166:11	I		
166:13	I		
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174:16	I		
174:18-174:20	I		
175:7-175:19	I	175:20-175:22	
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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194:18-195:7	I	126:13-18, 129:11-12, 129:15-130:3, 130:18-20, 130:22-131:5, 131:8-11, 131:13-15, 131:17-19, 132:1-14, 134:3-5, 195:8-11, 195:14-18	
195:20-195:22	I	126:13-18, 129:11-12, 129:15-130:3,	

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		130:18-20, 130:22-131:5, 131:8-11, 131:13-15, 131:17-19, 132:1-14, 134:3-5, 195:8-11, 195-14-18	
196:2-196:5	I	68:8-17, 68:22-69:2, 69:4-16, 70:14-15, 70:17-19, 71:4-9, 71:11-19, 72:20-73:4, 73:7, 73:14-17, 73:19-74:6, 74:8-12, 87:2-11, 87:13-14, 87:19-88:11, 197:9, 197:11-15, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
196:7-196:11	I		
196:13-196:15	I	68:8-17, 68:22-69:2, 69:4-16, 70:14-15, 70:17-19, 71:4-9, 71:11-19, 72:20-73:4, 73:7, 73:14-17, 73:19-74:6, 74:8-12, 87:2-11, 87:13-14, 87:19-88:11, 197:9, 197:11-15, 342:8-343:4, 343:7-8, 343:10-344:11,	

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		344:14-346:10, 346:12-348:5	
196:17-196:22	I	68:8-17, 68:22-69:2, 69:4-16, 70:14-15, 70:17-19, 71:4-9, 71:11-19, 72:20-73:4, 73:7, 73:14-17, 73:19-74:6, 74:8-12, 87:2-11, 87:13-14, 87:19-88:11, 197:9, 197:11-15, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
197:3-197:4	I	68:8-17, 68:22-69:2, 69:4-16, 70:14-15, 70:17-19, 71:4-9, 71:11-19, 72:20-73:4, 73:7, 73:14-17, 73:19-74:6, 74:8-12, 87:2-11, 87:13-14, 87:19-88:11, 197:9, 197:11-15, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
208:16-209:5	I		
210:10-210:14	I		
213:16-214:8	I	212:18-213:12, 37:10-11, 52:10-12, 2:14-15, 57:2-	I (Testimony @ 193:-10 does not include Question

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
214:13-217:13	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
217:16-217:21	I		
218:3	I		
218:5-218:6	I		
218:8-218:9	I		
218:12-218:14	I		
218:17-219:6	I		
225:17-225:21	I	226:6-9, 226:22-227:14, 227:17-18, 296:12-14, 295:17-22, 266:21, 267:1-6, 267:8-9	
226:2-226:4	I	226:6-9, 226:22-227:14, 227:17-18, 296:12-14, 295:17-22, 266:21, 267:1-6, 267:8-9	
226:10-226:12	I		
226:14-226:18	I		
226:20	I	226:22-227:2, 227:5-227:14, 227:17-227:18	
228:4-228:14	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11,	this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		344:14-346:10, 346:12-348:5	
228:22-229:10	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
229:12-229:17	I	229:19-20, 230:1-3	
230:5-230:6	I		
230:8-231:13	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
231:15-231:20	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11,	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
232:1-232:5	I		
232:8-232:9	I		
232:19-233:13	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
234:1-234:3			
234:11-235:1	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11,	this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		344:14-346:10, 346:12-348:5	
235:5-235:6	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-	

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
238:2-239:19	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10,	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
240:2-240:4	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14,	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
240:7-240:9	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1,	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
241:8-242:11	I	240:17-21, 241:1-3, 241:6-7, 226:6-9, 226:22-227:14, 227:17-18, 266:21, 267:1-6, 267:8-9, 295:12-14, 295:17-22	
242:13-242:22	I	226:6-9, 226:22-227:14, 227:17-18, 266:21, 267:1-6,	

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		267:8-9, 295:12-14, 295:17-22	
243:4-243:10	I	226:6-9, 226:22-227:14, 227:17-18, 266:21, 267:1-6, 267:8-9, 295:12-14, 295:17-22, 37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15,	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
243:12	I	226:6-9, 226:22-227:14, 227:17-18, 266:21, 267:1-6, 267:8-9, 295:12-14, 295:17-22, 37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
252:6-252:8	I	226:6-9, 226:22-227:14, 227:17-18, 266:21, 267:1-6, 267:8-9, 295:12-14, 295:17-22, 37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3,	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
252:12-252:16	I	226:6-9, 226:22-227:14, 227:17-18,	

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		266:21, 267:1-6, 267:8-9, 295:12-14, 295:17-22, 37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18,	

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
253:13-253:15	I	226:6-9, 226:22-227:14, 227:17-18, 266:21, 267:1-6, 267:8-9, 295:12-14, 295:17-22, 37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14,	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
254:13-254:20	I	226:6-9, 226:22-227:14, 227:17-18, 266:21, 267:1-6, 267:8-9, 295:12-14, 295:17-22, 37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
255:1-255:12	I	226:6-9, 226:22-227:14, 227:17-18, 266:21, 267:1-6, 267:8-9, 295:12-14, 295:17-22, 37:10-11, 52:10-	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14,	included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
255:14-255:19	I	226:6-9, 226:22-227:14, 227:17-18, 266:21, 267:1-6, 267:8-9, 295:12-14, 295:17-22, 37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20,	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
255:21	I	226:6-9, 226:22-227:14, 227:17-18, 266:21, 267:1-6, 267:8-9, 295:12-14, 295:17-22, 37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
259:22-261:9	I	31:22-33:1, 38:12-39:1, 39:12-18, 40:3-18, 41:1-42:1, 5:-14-18, 51:7-2:4	
261:12-261:15	I	226:6-9, 226:22-227:14, 227:17-18, 266:21, 267:1-6, 267:8-9, 295:12-14, 295:17-22	

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
261:17-262:4	I	226:6-9, 226:22-227:14, 227:17-18, 266:21, 267:1-6, 267:8-9, 295:12-14, 295:17-22	
262:6	I	226:6-9, 226:22-227:14, 227:17-18, 266:21, 267:1-6, 267:8-9, 295:12-14, 295:17-22	
262:19-263:2	I	226:6-9, 226:22-227:14, 227:17-18, 266:21, 267:1-6, 267:8-9, 295:12-14, 295:17-22	
263:6-264:2	I	226:6-9, 226:22-227:14, 227:17-18, 266:21, 267:1-6, 267:8-9, 295:12-14, 295:17-22	
264:6-264:7	I	226:6-9, 226:22-227:14, 227:17-18, 266:21, 267:1-6, 267:8-9, 295:12-14, 295:17-22	
264:9-264:13	I	226:6-9, 226:22-227:14, 227:17-18, 266:21, 267:1-6, 267:8-9, 295:12-14, 295:17-22	
264:16-264:18	I	226:6-9, 226:22-227:14, 227:17-18, 266:21, 267:1-6, 267:8-9, 295:12-14, 295:17-22	

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
266:8-266:15	I	226:6-9, 226:22-227:14, 227:17-18, 266:21, 267:1-6, 267:8-9, 295:12-14, 295:17-22	
266:19	I	226:6-9, 226:22-227:14, 227:17-18, 266:21, 267:1-6, 267:8-9, 295:12-14, 295:17-22	
267:21-268:2	I	226:6-9, 226:22-227:14, 227:17-18, 266:21, 267:1-6, 267:8-9, 295:12-14, 295:17-22	
268:4-268:13	I	226:6-9, 226:22-227:14, 227:17-18, 266:21, 267:1-6, 267:8-9, 295:12-14, 295:17-22	
268:18-269:4	I	226:6-9, 226:22-227:14, 227:17-18, 266:21, 267:1-6, 267:8-9, 295:12-14, 295:17-22	
269:6-269:10	I	226:6-9, 226:22-227:14, 227:17-18, 266:21, 267:1-6, 267:8-9, 295:12-14, 295:17-22	
269:14-270:1	I		
270:6-270:12	I		
270:14-270:19	I		
270:21	I		
271:7-271:8	I		
271:10-271:17	I		

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
271:19-272:3	I	226:6-9, 226:22-227:14, 227:17-18, 266:21, 267:1-6, 267:8-9, 295:12-14, 295:17-22	
272:6-272:7	I	226:6-9, 226:22-227:14, 227:17-18, 266:21, 267:1-6, 267:8-9, 295:12-14, 295:17-22	
272:20-272:21	I	342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
273:1-273:3	I	342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
273:8-273:9	I	342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
273:11-274:8	I	342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
274:10-274:21	I		
276:3-276:14			
276:20-277:15	I	68:8-17, 68:22-69:2, 69:4-16, 70:14-15, 70:17-19, 71:4-9, 71:11-	

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		19, 72:20-73:4, 73:7, 73:14-17, 73:19-74:6, 74:8-12, 87:2-11, 87:13-14, 87:19-88:11, 197:9, 197:11-15	
277:17-278:3	I	68:8-17, 68:22-69:2, 69:4-16, 70:14-15, 70:17-19, 71:4-9, 71:11-19, 72:20-73:4, 73:7, 73:14-17, 73:19-74:6, 74:8-12, 87:2-11, 87:13-14, 87:19-88:11, 197:9, 197:11-15	
278:5-278:14	I	68:8-17, 68:22-69:2, 69:4-16, 70:14-15, 70:17-19, 71:4-9, 71:11-19, 72:20-73:4, 73:7, 73:14-17, 73:19-74:6, 74:8-12, 87:2-11, 87:13-14, 87:19-88:11, 197:9, 197:11-15	
278:16-279:11	I	68:8-17, 68:22-69:2, 69:4-16, 70:14-15, 70:17-19, 71:4-9, 71:11-19, 72:20-73:4, 73:7, 73:14-17, 73:19-74:6, 74:8-12, 87:2-11,	

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		87:13-14, 87:19-88:11, 197:9, 197:11-15	
279:13-279:19	I	342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
279:21-280:4	I	342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
280:6-280:9	I	342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
280:11-280:14	I	342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
280:16-281:8	I	342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
281:16-281:17	I	342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
281:19-282:7	I	342:8-343:4, 343:7-8, 343:10-344:11, 344:14-	

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		346:10, 346:12-348:5	
282:11-282:12	I	226:6-9, 226:22-227:14, 227:17-18, 266:21, 267:1-6, 267:8-9, 295:12-14, 295:17-22	
282:15	I	226:6-9, 226:22-227:14, 227:17-18, 266:21, 267:1-6, 267:8-9, 295:12-14, 295:17-22	
282:17-282:18	I		
282:21-283:2	I		
283:5-283:18	I	342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
283:21-284:15	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1,	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
284:18-285:12	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17,	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
285:16-286:2	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11,	this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		344:14-346:10, 346:12-348:5	
286:5-286:13	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
289:2-289:5	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10,	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
289:7-289:9	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14,	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
290:5-290:7	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1,	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
290:9-290:12	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17,	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
290:14-290:18	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11,	this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		344:14-346:10, 346:12-348:5	
290:20-291:8	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
291:13-291:15	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10,	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
291:17-292:2	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14,	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
292:4-292:8	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1,	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
292:10-292:11	I		
293:9-293:12	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7,	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
293:14-293:17	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15,	I (Testimony @ 193:-10 does not include Question @ 193:15-19.

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11,	Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		344:14-346:10, 346:12-348:5	
293:21-294:4	I		
294:8-294:14	I		
294:16	I		
295:3-295:6	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19, 132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14,	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
295:9-295:10	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
296:2-296:4	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11,	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
296:7-296:18	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3,	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
296:20-297:8	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3,	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2, 225:-12, 22:14, 226:6-9, 226:22-227:14, 227:17-18, 235:8-10, 235:13-18, 289:11-12, 289:14, 189:20-290:3, 295:12-14, 295:17-22, 342:8-343:4, 343:7-8, 343:10-344:11, 344:14-346:10, 346:12-348:5	
297:12-297:18	I	37:10-11, 52:10-12, 2:14-15, 57:2-	I (Testimony @ 193:-10 does not

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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298:6-298:15			
298:20-299:11	I	299:16-300:9	
348:18-348:19	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10, 200:12-18, 202:5-8, 201:11-20, 201:22-202:7, 203:6-7, 203:9-10, 224:10-12, 224:15, 224:19-225:2,	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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349:1-349:20	I	37:10-11, 52:10-12, 2:14-15, 57:2-9, 57:11-13, 61:3-4, 61:6-13, 61:15, 73:14-17, 73:19-74:6, 74:8-12, 97:12-98:19, 98:22-99:3, 100:22-101:1, 101:3-13, 102:5-7, 102:10-17, 114:13-20, 115:1-8, 115:10, 129:11-12, 129:15-130:3, 131:13-15, 131:17-19:132:1-14, 147:21-148:1, 148:3-7, 173:13-15, 173:17, 193:-10, 195:8-11, 195:14-18, 197:9, 197:11-15, 197:20-198:14, 198:18-19, 199:-6, 199:8-11, 200:10,	I (Testimony @ 193:-10 does not include Question @ 193:15-19. Please confirm this should be included in P's counters).

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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350:1-350:6	I	68:8-17, 68:22-69:2, 69:4-16, 70:14-15, 70:17-19, 71:4-9, 71:11-19, 72:20-73:4, 73:7, 73:14-17, 73:19-74:6, 74:8-12, 87:2-11, 87:13-14, 87:19-88:11, 197:9, 197:11-15	

Deponent: Mihael Polymeropoulos, M.D. (November 18, 2020)

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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27:18-28:7	I, 701	28:21–29:5	
32:13-33:5	I	45:23–46:1, 46:3–9	
33:16-35:1			
35:4-35:10			
35:12-35:19			
36:15-19	I	36:20–21, 36:23–37:3	
37:5-37:12			
37:17-39:8	602, 701		
39:10-39:24	I	39:25–40:2	
40:3-40:25	I	39:25–40:2	
41:16-41:24			
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50:1-50:7			
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62:5-62:6	I, 602, 701	61:16–18, 61:20–62:3	
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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80:15-81:17	I	76:9-15, 77:24-78:5, 78:7-10, 78:12-16, 78:18-80:13	

Deponent: Mihael Polymeropoulos, M.D. (December 20, 2019)

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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50:22-52:3	I	52:5-10, 58:21-59:7, 59:9-60:11, 60:20-61:15	
52:11-53:1	I	52:5-10	
54:1-54:18	I	53:2-17, 53:19-21, 54:20-22, 55:3-13, 55:15-	

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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91:11-91:15	I	91:16–92:13	
101:18-102:15	701		
104:16-104:19	I	104:20–105:12	
105:13-105:19	I	104:20–105:12	
107:10-107:14	I		
108:4-109:20	Colloquy		
110:15-111:12			
111:16-113:15	113:16–18, 113:21–114:2		
114:4-114:21	I	115:8–116:3	
116:4-117:12	I, Colloquy	115:8–116:3, 140:4–5, 140:8–9, 140:11–18, 141:17–142:11, 142:13–17	
117:14-117:22	I	115:8–116:3, 140:4–5, 140:8–9, 140:11–18, 141:17–142:11, 142:13–17	
118:12-121:5	Colloquy		

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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127:6-128:3	I, 701, Colloquy	126:11-127:5	
128:19-129:1	I, 701	126:11-127:5	
129:5-129:14	701, Colloquy		
131:3-131:12	I	131:15-132:1, 132:6-9	
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138:2-138:9	I	139:9-20	
138:11-138:21	I, Colloquy	139:9-20	
139:1-139:8	I	139:9-20	
141:4-141:15	I, Colloquy	140:4-5, 140:8-9, 140:11-18, 141:17-142:11, 142:13-17	
142:21-142:22	I	143:1-3	
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230:15-231:8	I, 602, 701	187:2–20	
231:10-231:11			
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242:3-242:12	I, 701	241:6–242:2	
248:6-248:19	701		
249:4-249:9	701		
250:3-250:10	701		
252:15-254:7			
255:2-256:1	I, Colloquy	245:12–255:1	
259:14-260:21	602		
266:10-266:11	I	266:19–267:7	
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267:11-268:20	I	269:3–270:9	
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272:16-272:19	403		
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281:1-281:9	I		
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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287:8-288:9	I	286:18–287:7, 288:10–20	
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294:6—294:11	I	294:4–5	
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296:2-296:22	602		
299:20-301:2	602		
301:6-301:22			
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Deponent: Stephen Swinton (December 10, 2019)

Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
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Defendant's Designation	Plaintiff's Objections	Plaintiff's Counter-Designation	Defendant's Objections
		14-20, 198:23-199:5, 202:13-204:12, 204:15-205:23, 209:1-6	
202:13-204:18	I, Colloquy	44:24-46:1, 97:10-17, 103:10-25, 106:7-107:10, 108:14-23, 156:7-24, 157:25-158:21, 159:1-4, 160-24-161:1, 161:5, 204:20-205:23	I, IC, V, S, AF
204:20-206:2	I	44:24-46:1, 97:10-17, 103:10-25, 106:7-107:10, 108:14-23, 156:7-24, 157:25-158:21, 159:1-4, 160-24-161:1, 161:5, 202:13-203:24	I, IC, V, S, AF
209:15-210:15	I	44:24-46:1, 85:14-22, 88:18-90:25, 103:10-25, 122:9-123:10, 124:9-24, 126:19-24, 127:1-15, 130:5-10, 130:13-131:2, 131:4-18, 206:25-208:11	I, IC, V, S, AF

Abbreviation	Basis for Objection	Rule
403	Prejudicial	FRE 403
V	Vague and ambiguous	
AF	Assuming facts not in evidence	
E or 701 or 702/703	Calls for expert opinion, improper testimony of a lay witness	FRE 701-702
F or 602	Lacks foundation	FRE 602, 901
H or 802	Hearsay	FRE 801-802
HYP	Improper hypothetical	FRE 501-502
I	Incomplete	FRE 106
MIS	Mischaracterizes evidence/testimony or is misleading	FRE 611
OBJ	Includes Attorney Objections	
R or 402 or NR	Relevance	FRE 402
S	Calls for speculation	FRE 401-403, 602, 701
C	Compound	
Scope	Outside the scope of 30(b)(6) designation	
NQP or MA	No question posed	
NA	No answer	
A&A	Asked and answered	
NS	Nonsensical	

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

VANDA PHARMACEUTICALS
INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA,
INC., et al.,

Defendants.

C.A. No. 18-651-CFC
(Consolidated)

Exhibit 10 – Plaintiff’s Trial Exhibit List

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

(C.A. No. 18-00651-CFC)

Vanda Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc., et al.

Plaintiff's Trial Exhibit List

<u>Exhibit Number</u>	<u>Date</u>	<u>Description</u>	<u>Beginning Bates Number</u>	<u>Ending Bates Number</u>	<u>Defendants' Objections</u>	<u>Admitted</u>
1	4/13/2017	Declaration of Mihael Polymeropoulos under 37 C.F.R. § 1.132	VNDHTLZ 00000806	VNDHTLZ 00000832		
2	10/31/2015	Lockley et al. <i>Tasimelteon for Non-24-hour Sleep-Wake Disorder in Totally Blind People (SET and RESET): Two Multicentre, Randomised, Double-masked, Placebo-controlled Phase 3 Trial, Lancet 2015; 386: 1754-64</i>	VNDHTLZ 01643645	VNDHTLZ 01643655		
3	8/5/2015	Supplement to: Lockley SW, Dressman MA, Licamele L, et al. <i>Tasimelteon for non-24-hour sleep-wake disorder in totally blind people (SET and RESET): two multicentre, randomised, double-masked, placebo-controlled phase 3 trials.</i>	VNDHTLZ 01643629	VNDHTLZ 01643629		
4	11/14/2013	Food & Drug Administration, Peripheral and Central Nervous System Drugs Advisory Committee Meeting Transcript	VNDHTLZ 00568949	VNDHTLZ 00569243		
5	2/22/2017	Emens and Eastman, <i>Diagnosis and Treatment of Non-24-h Sleep-Wake Disorder in the Blind</i> , Drugs at 9 (2017)	VNDHTLZ 03083556	VNDHTLZ 03083569		
6	1997	Kaminsky And Zhang, Human P450 Metabolism Of Warfarin, 73 Pharmacology & Therapeutics 67	VNDHTLZ 03091801	VNDHTLZ 03091808		
7	4/7/2020	U.S. Patent No. 10,611,744	VNDHTLZ 03101216	VNDHTLZ 03101225		
8	2/25/2020	File History to U.S. Patent No. 10,071,977	VNDHTLZ 03101226	VNDHTLZ 03101226		
9	9/6/2018	File History to U.S. Patent No. 10,611,744	VNDHTLZ 03100649	VNDHTLZ 03101215		
10	4/30/2012	Provisional Application 61/640,067	VNDHTLZ 00007465	VNDHTLZ 00007492		
11	6/14/2012	Provisional Application 61/650,455	VNDHTLZ 00007493	VNDHTLZ 00007570		
12	7/20/2012	Provisional Application 61/650,458	VNDHTLZ 00007571	VNDHTLZ 00007658		

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

(C.A. No. 18-00651-CFC)

Vanda Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc., et al.

Plaintiff's Trial Exhibit List

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13	10/15/2012	Provisional Application 61/714,149	VNDHTLZ 00007659	VNDHTLZ 00007767		
14	12/18/2012	Provisional Application 61/738,985	VNDHTLZ 00007768	VNDHTLZ 00007930		
15	12/18/2012	Provisional Application 61/738,987	VNDHTLZ 00007931	VNDHTLZ 00008061		
16		Provisional Application 61/755,896	VNDHTLZ 00008062	VNDHTLZ 00008198		
17	11/12/2013	Provisional Application 61/903,354	VNDHTLZ 00008199	VNDHTLZ 00008433		
18	1/14/2014	Provisional Application 61/927,465	VNDHTLZ 03090120	VNDHTLZ 03090201		
19	2/12/2014	Provisional Application 61/938,922	VNDHTLZ 02679500	VNDHTLZ 02679535		
20	12/4/2014	Provisional Application 62/087,394	VNDHTLZ 02679536	VNDHTLZ 02679577		
21	3/20/2013	PCT Application No. U.S. 2013/023315	VNDHTLZ 00008434	VNDHTLZ 00009480		
22	1/11/2014	PCT Application No. U.S. 2013/076311	VNDHTLZ 00009481	VNDHTLZ 00010606		
23	3/11/2021	Apotex Presentation, 3 Way Labeling Comparison Prescribing Information	APO-TASI-0131622	APO-TASI-0131653		
24	1/2018	Tasimelteon capsules 20mg, Label	TEVA_TAS-000000101	TEVA_TAS-000000110		
25	7/2018	Tasimelteon Capsules 20Mg, Label	TEVA_TAS-000018756	TEVA_TAS-000018764		
26	10/1/2019	Tasimelteon Capsules 20 MG Label	TEVA_TAS-000089209	TEVA_TAS-000089217		
27	10/2019	Tasimelteon Capsules, 20 mg, Label	TEVA_TAS-000089218	TEVA_TAS-000089228		
28	1/31/2018	Apotex, 2 Way Labeling Comparison	APO-TASI-0000430	APO-TASI-0000445		
29	7/12/2018	[REDACTED]	APO-TASI-0006327	APO-TASI-0006330		
30	4/20/2016	[REDACTED]	APO-TASI-0073322	APO-TASI-0073330		

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

(C.A. No. 18-00651-CFC)

Vanda Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc., et al.

Plaintiff's Trial Exhibit List

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31	7/13/2016	[REDACTED]	APO-TASI-0075657	APO-TASI-0075659		
32	3/8/2017	[REDACTED]	APO-TASI-0078920	APO-TASI-0078922		
33	4/27/2017	[REDACTED]	APO-TASI-0100203	APO-TASI-0100209		
34	2/11/2016	[REDACTED]	APO-TASI-0112269	APO-TASI-0112285		
35	3/30/2017	[REDACTED]	APO-TASI-0127321	APO-TASI-0127332		
36	2/10/2017	[REDACTED]	APO-TASI-0127354	APO-TASI-0127367		
37	10/2017	[REDACTED]	APO-TASI-0129275	APO-TASI-0129285		
38	11/16/2018	[REDACTED]	APO-TASI-0129319	APO-TASI-0129325		
39	6/1/2019	[REDACTED]	APO-TASI-0129491	APO-TASI-0129504		
40	1/31/2018	[REDACTED]	APO-TASI-0130082	APO-TASI-0130084		
41	8/23/2019	[REDACTED]	APO-TASI-0130085	APO-TASI-0130086		
42	10/2019	Tasimelteon Capsules 20Mg, Label	APO-TASI-0131342	APO-TASI-0131351		
43	10/2019	Tasimelteon Capsules, 20 mg Minor Amendment - Labeling	APO-TASI-0131380	APO-TASI-0131380		
44	10/18/2019	[REDACTED]	APO-TASI-0131381	APO-TASI-0131381		
45	12/9/2019	[REDACTED]	APO-TASI-0131418	APO-TASI-0131419		
46	12/2002	FDA Guidance For Industry On Food-Effect Bioavailability And Fed Bioequivalence Studies	TASI-DEF-0002528	TASI-DEF-0002539		

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

(C.A. No. 18-00651-CFC)

Vanda Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc., et al.

Plaintiff's Trial Exhibit List

<u>Exhibit Number</u>	<u>Date</u>	<u>Description</u>	<u>Beginning Bates Number</u>	<u>Ending Bates Number</u>	<u>Defendants' Objections</u>	<u>Admitted</u>
47	1/11/2018	Letter from J. Liu to FDA DMF Staff re: Tasimelteon	TEVA_TAS-000000011	TEVA_TAS-000000011		
48	1/26/2018	1.12.12 Comparison Between Generic Drug and Reference Listed Drug	TEVA_TAS-000000029	TEVA_TAS-000000030		
49	1/31/2018	Application to Market a New or Abbreviated New Drug or Biologic for Human Use	TEVA_TAS-000000048	TEVA_TAS-000000054		
50	1/31/2018	Letter from D. DeCicco to FDA re: Pre -Assigned ANDA # 211601 / Sequence # 0001 Tasimelteon Capsules, 20 mg	TEVA_TAS-000000058	TEVA_TAS-000000061		
51	1/26/2018	Package Outsert Side by Side Comparison	TEVA_TAS-000000075	TEVA_TAS-000000088		
52	11/3/2017	U.S. Agent Appointment Letter	TEVA_TAS-000000113	TEVA_TAS-000000113		
53	1/31/2018	Tasimelteon, Drug Substance	TEVA_TAS-000000132	TEVA_TAS-000000198		
54		2.3.S.1 General Information [Tasimelteon, [REDACTED]]	TEVA_TAS-000000199	TEVA_TAS-000000267		
55	1/31/2018	Tasimelteon Capsules 20 Mg, Drug Product	TEVA_TAS-000000269	TEVA_TAS-000000371		
56	1/31/2018	2.7 Clinical Summary	TEVA_TAS-000000498	TEVA_TAS-000000519		

IN THE UNITED STATES DISTRICT COURT

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57	1/25/2018	Product Development Report Of Tasimelteon Capsules 20 Mg	TEVA_TAS-000000655	TEVA_TAS-000000755		
58	1/12/2018	Reprocessing Statement Tasimelteon Capsules 20Mg	TEVA_TAS-000000833	TEVA_TAS-000000833		
59	1/6/2015	Anhydrous Lactos Us Nf Standard Test Procedure	TEVA_TAS-000000995	TEVA_TAS-000001007		
60	1/30/2018	Certificate of Analysis, Tasimelteon Capsules 20mg	TEVA_TAS-000001561	TEVA_TAS-000001589		
61		Residual Solvents Evaluation [Tasimelteon Capsules, 20mg]	TEVA_TAS-000001656	TEVA_TAS-000001657		
62	1/30/2018	Photostability Study On Tasimelteon Capsules 20 Mg	TEVA_TAS-000001847	TEVA_TAS-000001889		
63	1/31/2018	3.2.S.2. Manufacture [Tasimelteon, REDACTED]	TEVA_TAS-000002332	TEVA_TAS-000002333		

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

(C.A. No. 18-00651-CFC)

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64	11/3/2017	Tasimelteon - cGMP Statement	TEVA_TAS-000002334	TEVA_TAS-000002334		
65	1/26/2018	Manufacturing Process Development [Tasimelteon,	TEVA_TAS-000002338	TEVA_TAS-000002338		
66		3.2.S.3 Characterization, Impurities	TEVA_TAS-000002340	TEVA_TAS-000002342		
67	1/15/2018	Certificate of Analysis, Tasimelteon	TEVA_TAS-000003048	TEVA_TAS-000003048		
68	6/7/2017	Certificate of Analysis, Tasimelteon	TEVA_TAS-000003050	TEVA_TAS-000003075		
69		3.2.S.4 Control of Drug Substance	TEVA_TAS-000003103	TEVA_TAS-000003109		
70	12/29/2017	Final Clinical Study Report - Study #BE-1740-16 - Tasimelteon Capsule, 20 mg	TEVA_TAS-000005392	TEVA_TAS-000005456		
71	1/22/2018	Clinical Study Report: Study # BE-1740-16 Tasimelteon Capsule, 20mg, Protocol and Protocol Amendments	TEVA_TAS-000007871	TEVA_TAS-000007976		
72	3/9/2018	Letter from A. Inniss (FDA) to D. DeCicco (Teva) re: ANDA Tasimelteon Capsules, 20 mg Information Request	TEVA_TAS-000018641	TEVA_TAS-000018643		
73	3/9/2018	Response to FDA Request for Information- Quality	TEVA_TAS-000018645	TEVA_TAS-000018645		
74	3/12/2018	Letter from D. DeCicco to FDA re: ANDA # 211601 / Sequence # 0002 Tasimelteon Capsules, 20 mg Information Request Quality	TEVA_TAS-000018653	TEVA_TAS-000018653		
75	3/28/2018	Letter from D. DeCicco to U.S. Food & Drug Administration re Patent Amendment: Receipt of Notice and 45- Day Clock	TEVA_TAS-000018678	TEVA_TAS-000018679		
76	5/8/2018	Letter from D. DeCicco to U.S. Food & Drug Administration re Patent Amendment: Legal Update	TEVA_TAS-000018724	TEVA_TAS-000018725		

IN THE UNITED STATES DISTRICT COURT

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Plaintiff's Trial Exhibit List

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77	4/29/2013	Vanda Clinical Study Report "Tasimelteon VP-VEC-162-3203 A Randomized Withdrawal Study to Demonstrate the Maintenance of Effect of 20 mg Tasimelteon in the Treatment of N24HSWD"	VNDHTLZ 00254220	VNDHTLZ 00254313		
78	7/16/2018	Letter from A. Inniss (FDA) to D. DeCicco (Teva) re: ANDA Tasimelteon Capsules, 20 mg	TEVA_TAS-000018728	TEVA_TAS-000018733		
79	7/24/2018	Letter from D. DeCicco to FDA re: ANDA # 211601 / Sequence # 0005 Tasimelteon Capsules, 20 mg	TEVA_TAS-000018734	TEVA_TAS-000018735		
80	7/18/2018	Letter from C. Gentles (FDA) to D. DeCicco (TEVA) re: ANDA Discipline Review Letter	TEVA_TAS-000018736	TEVA_TAS-000018737		
81	7/12/2018	Letter from U.S. Food & Drug Administration to D. DeCicco re Discipline Review Letter	TEVA_TAS-000018750	TEVA_TAS-000018753		
82	7/12/2018	Discipline Review Letter/ Labeling	TEVA_TAS-000018775	TEVA_TAS-000018776		
83	7/25/2018	Email from C. Lemley to L. Moulder re ANDA #211601 - Tasimelteon Capsules, 20mg - Response to Labeling Discipline Review Letter	TEVA_TAS-000018790	TEVA_TAS-000018791		
84	7/12/2018	Letter from USFDA to D. DeCicco re New Drug Application Discipline Review Letter	TEVA_TAS-000018796	TEVA_TAS-000018799		
85	10/24/2018	Letter from D. DeCicco to U.S. Food & Drug Administration re Patent Amendment: Certification to U.S. Patent 10,071,977	TEVA_TAS-000018826	TEVA_TAS-000018826		
86	11/9/2018	Letter from D. McKan (FDA) to D. DeCicco (Teva) re: ANDA Tasimelteon Capsules, 20 mg	TEVA_TAS-000018830	TEVA_TAS-000018836		
87	10/30/2018	Letter from D. DeCicco to U.S. Food & Drug Administration re Patent Amendment: Receipt of Notice	TEVA_TAS-000018850	TEVA_TAS-000018850		
88	2/4/2019	Patent Certification [Tasimelteon Capsules, 20 MG]	TEVA_TAS-000018875	TEVA_TAS-000018876		

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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89	2/6/2019	Letter from U.S. Food & Drug Administration to D. DeCicco re Patent Amendment: Certification to U.S. Patent 10149829	TEVA_TAS-000018877	TEVA_TAS-000018877		
90	2/13/2019	Letter from D. DeCicco to U.S. Food & Drug Administration re Patent Amendment: Receipt of Notice	TEVA_TAS-000018891	TEVA_TAS-000018891		
91	1/14/2018	Description Of Manufacturing Process And Process Controls	TEVA_TAS-000018923	TEVA_TAS-000018925		
92	11/5/2017	[REDACTED] - Tasimelteon - 3.2.S.3.2 Impurities	TEVA_TAS-000018926	TEVA_TAS-000019052		
93	11/2/2017	[REDACTED] - Tasimelteon - 3.2.5.4 Control of drug substance	TEVA_TAS-000019086	TEVA_TAS-000019087		
94	8/1/2019	[REDACTED] - 3.2.S.2.2 Description of manufacturing process and process controls	TEVA_TAS-000020010	TEVA_TAS-000020013		

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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95	7/31/2019	<div style="background-color: black; height: 1.2em; width: 150px; margin-bottom: 2px;"></div> Tasimelteon - 3.2.S.3.2 Impurities	TEVA_TAS-000020014	TEVA_TAS-000020049		
96	7/6/2019	<div style="background-color: black; height: 1.2em; width: 150px; margin-bottom: 2px;"></div> Tasimelteon - 3.2.S.4 Control of drug substance	TEVA_TAS-000020050	TEVA_TAS-000020051		
97	7/31/2019	<div style="background-color: black; height: 1.2em; width: 150px; margin-bottom: 2px;"></div> Tasimelteon - 3.2.S.4.2 Analytical procedures	TEVA_TAS-000020052	TEVA_TAS-000020065		
98	12/22/2016	3.2.S.4.3.2 Analytical Method Validation for Determination of Related Substances for Tasimelteon by HPLC	TEVA_TAS-000020066	TEVA_TAS-000020147		

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99	6/24/2019	[REDACTED] - Tasimelteon - 3.2.S.4.3.7 Analytical method supplemental validation for determination	TEVA_TAS-000020148	TEVA_TAS-000020209		
100	7/31/2019	[REDACTED] - Tasimelteon - 3.2.S.4.4 Batch analysis	TEVA_TAS-000020210	TEVA_TAS-000020215		
101	1/23/2014	Center for Drug Evaluation and Research - Application Number: 2056770orig1s000 Summary Review	TEVA_TAS-000020227	TEVA_TAS-000020237		
102	10/2010	Cowen Pharmaceutical Research Team, <i>Therapeutic Categories Outlook</i>	TEVA_TAS-000020343	TEVA_TAS-000021782		
103	1/31/2018	Letter from D. DeCicco to the Center for Drug Evaluation and Research re Pre-Assigned ANDA #211601 / Sequence #0001 Tasimelteon Capsules, 20 mg	TEVA_TAS-000031942	TEVA_TAS-000031945		
104	1/31/2018	Tasimelteon Capsules, 20,g Assessment	TEVA_TAS-000031946	TEVA_TAS-000031948		
105	3/10/2017	Email from H. Godwialla to J. Gaonkar re Test License and Manufacturing Capsules 20mg	TEVA_TAS-000032272	TEVA_TAS-000032289		
106	3/10/2017	Tasimelteon Capsules, License Requirements	TEVA_TAS-000032274	TEVA_TAS-000032277		
107	12/2014	Hetlioz, (tasimelteon) capsules 20mg, Label	TEVA_TAS-000032278	TEVA_TAS-000032289		

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108	2/8/2017	Tasimelteon Capsules, License Requirements	TEVA_TAS-000033064	TEVA_TAS-000033068		
109	10/6/2017	Email from J. Sivasubramanian to H. Godiwalla re Tasimelteon Capsules 20mg - Trade Dess with attachments	TEVA_TAS-000033887	TEVA_TAS-000033897		
110	9/6/2017	Email from R. Kadam to R. Thatte re Tasimelteon Capsules 20mg - Trade Dess with attachment	TEVA_TAS-000034502	TEVA_TAS-000034512		
111	7/13/2017	Email from K. Wazare to C. Shah re Lead Formulation Check list for Tasimelteon Capsules 20 mg	TEVA_TAS-000034978	TEVA_TAS-000034980		
112	6/28/2017	Email from A. Rout to K. Shaha re Tasimelteon Capsules 20 mg for IIG Clearance	TEVA_TAS-000034981	TEVA_TAS-000034981		
113	6/28/2017	Certification of Ink per Capsule and Elemental Iron Content in Hard Gelatin Capsule Shells	TEVA_TAS-000034984	TEVA_TAS-000034984		
114	6/28/2017	Certification of Ink per Capsule and Elemental Iron Content in Hard Gelatin Capsule Shells	TEVA_TAS-000034985	TEVA_TAS-000034985		
115	3/15/2018	Letter from U.S. Food & Drug Administration to D. DeCicco re Paragraph IV Acknowledgement ANDA Receipt	TEVA_TAS-000036373	TEVA_TAS-000036380		
116	1/29/2018	Email from J. Pawar to P. Shetty re ANDA 2018 Tasimelteon Capsules 20 mg Open Items	TEVA_TAS-000036561	TEVA_TAS-000036564		
117	12/1/2016	[REDACTED] - TSM-IMI-001 - Certificate	TEVA_TAS-000036608	TEVA_TAS-000036620		
118	1/24/2018	Email from M. Cui to K. Jinturkar re Draft Tasimelteon capsules 20mg PDR with attachment	TEVA_TAS-000036695	TEVA_TAS-000036697		
119	1/23/2018	Email from A. Kaushik to A. Raikar re Tasimelteon Capsules - CMC Contact	TEVA_TAS-000037128	TEVA_TAS-000037135		
120	1/25/2018	Email from A. Rout to R. Phale re: Tasimeltion DMF	TEVA_TAS-000040273	TEVA_TAS-000040284		

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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Vanda Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc., et al.

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121	1/15/2018	Email from R. Chhatani to A. Antarkar re: Tasimelteon with attachments	TEVA_TAS-000042115	TEVA_TAS-000042123		
122	1/25/2018	Email from L. Jambhale to S. Harhale re DP Stability Testing- Tasimelteon	TEVA_TAS-000052300	TEVA_TAS-000052301		
123	1/23/2018	Email from B. Salunkhe to R. Chhatani re: Tasimelction DMF	TEVA_TAS-000053534	TEVA_TAS-000053541		
124	10/10/2016	Email from R. Ashutosh to C. Priti re Tasimelteon Capsules 20mg Import License with attachments	TEVA_TAS-000053986	TEVA_TAS-000053990		
125	12/2014	Hetlioz (tasimelteon) capsules, 20 mg, Label	TEVA_TAS-000053993	TEVA_TAS-000054004		
126	9/4/2017	Email from A. Rout to R. Thatte re: Tasimelteon Capsules 20 mg - Trade Dess with attachment	TEVA_TAS-000056494	TEVA_TAS-000056502		
127	8/4/2017	Email from M. Barot to J. Derstine re Team Intro and Overview of India/Goa ANDA Submissions	TEVA_TAS-000057195	TEVA_TAS-000057200		
128	3/14/2018	Email from S. Parihar to J. Delgaudio re Discussion and status updates of pending deficiency comments (DL's) from health agencies and their responses - Status as on 14 March 2018	TEVA_TAS-000057256	TEVA_TAS-000057266		
129	3/2/2018	Letter from U.S. Food & Drug to D. DeCicco re Information Request	TEVA_TAS-000057267	TEVA_TAS-000057268		
130	3/8/2018	Letter from U.S. Food & Drug Administration to J. Derstine re Information Request	TEVA_TAS-000057269	TEVA_TAS-000057271		
131	3/9/2018	Letter from U.S. Food & Drug Administration to D. DeCicco re Information Request	TEVA_TAS-000057282	TEVA_TAS-000057284		
132	11/2/2011	Bioequivalence Amendment	TEVA_TAS-000057303	TEVA_TAS-000057309		
133	3/12/2018	Email from S. Parihar to D. DeCicco re Information Request: ANDA 211601 with attachment	TEVA_TAS-000057365	TEVA_TAS-000057369		
134	3/9/2018	[REDACTED] Tasimelteon	TEVA_TAS-000057374	TEVA_TAS-000057380		
135	3/9/2018	[REDACTED] - Tasimelteon	TEVA_TAS-000057394	TEVA_TAS-000057399		

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136	3/9/2018	Email from S. Tomsy to D. DeCicco re: Information Request: ANDA 211601	TEVA_TAS-000057400	TASI-DEF-0020362		
137	1/29/2018	Certificate of Analysis, Tasimelteon	TEVA_TAS-000057477	TEVA_TAS-000057502		
138	1/30/2018	Email from J. Delgaudio to D. DeCicco re: GDUFA ANDA Fee Approval Needed - 211601 Tasimelteon Capsules, 20 mg	TEVA_TAS-000057540	TEVA_TAS-000057541		
139	3/10/2017	Email from H. Godiwalla to B. Shah re K-7 NPD with attachment	TEVA_TAS-000058520	TEVA_TAS-000058536		
140	1/29/2018	Email from H. Shiravadekar to H. Godiwalla re NPD Slides with attachment	TEVA_TAS-000059230	TEVA_TAS-000059304		
141	1/17/2018	Email from A. Mehta to R. Phale re: Tasimelteon Quality Agreement Details	TEVA_TAS-000060798	TEVA_TAS-000060799		
142	1/8/2018	Email from H. Godiwalla to A. Antarkar re K-7 NPD Meeting - Pre - Read with attachment	TEVA_TAS-000062782	TEVA_TAS-000062859		
143	10/13/2017	Email from H. Godiwalla to A. Antarkar re K-7 NPD Meeting - 11 Oct 2017 with attachment	TEVA_TAS-000063468	TEVA_TAS-000063557		
144	1/17/2018	Email from B. Salunkhe to R. Helwade et al. re Tasimelteon DMF	TEVA_TAS-000066570	TEVA_TAS-000066575		
145	1/17/2018	Certificate Of Analysis	TEVA_TAS-000066577	TEVA_TAS-000066582		
146	11/27/2017	Email from M. Avhad to R. Patil re: ANDA_Tasimelteon Capsules 20mg- Documents Request	TEVA_TAS-000068042	TEVA_TAS-000068044		
147	12/18/2017	Email from R. Patil to M. Avhad re ANDA_Tasimelteon 20mg- Documents Request	TEVA_TAS-000069555	TEVA_TAS-000069557		
148	12/19/2016	TDP of Tasimelteon	TEVA_TAS-000082137	TEVA_TAS-000082172		
149	11/5/2017	Zhejiang; Ausun Pharmaceutical Co., Ltd. - Tasimelteon - 3.2.S.4.2 Analytical procedures	TEVA_TAS-000082213	TEVA_TAS-000082224		
150	6/10/2018	List of Changes of Open Part of USDMF Between Amendment Version 1.2 and Amendment Version 1.1	TEVA_TAS-000082238	TEVA_TAS-000082248		

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151	1/16/2018	Email from A. Kaushik to A. Rout re: [REDACTED] [REDACTED]	TEVA_TAS-000082345	TEVA_TAS-000082346		
152	7/6/2017	Watson Pharma Private Limited. - Tasimelteon - Certificate of Analysis	TEVA_TAS-000082485	TEVA_TAS-000082486		
153	7/13/2018	Letter From A. Inniss To W. Ou Re Drug Master File #032077 For Tasimelteon	TEVA_TAS-000082563	TEVA_TAS-000082569		
154	3/2019	Tasimelteon Capsules -20 mg, Complete Response Letter	TEVA_TAS-000088686	TEVA_TAS-000088690		
155	10/14/20019	Patent Certification [Tasimelteon Capsules, 20 MG]	TEVA_TAS-000088754	TEVA_TAS-000088755		
156	10/31/2019	Letter from D. DeCicco to FDA re: Extension Request Pertaining to November 9, 2018 Complete Response Letter	TEVA_TAS-000088787	TEVA_TAS-000088787		
157	11/9/2018	Letter from D. Mckan to D. DeCicco re Abbreviated New Drug Application (ANDA)	TEVA_TAS-000088788	TEVA_TAS-000088794		
158	11/25/2019	Tasimelteon Product Information - Tasimelteon (Hetlioz) OralCapsules20mg (with Redactions)	TEVA_TAS-000088795	TEVA_TAS-000089014		
159	2/2/2015	Strategy - US_012767 (Tasmimelteon - Oral Capsules Hetlioz	TEVA_TAS-000089015	TEVA_TAS-000089029		
160	1/2/2020	Patent Certification [Tasimelteon Capsules, 20 MG]	TEVA_TAS-000089091	TEVA_TAS-000089092		
161	7/11/2019	Tasimelteon Analytical Method Validation Report	TEVA_TAS-000089694	TEVA_TAS-000089949		

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162	9/28/2020	Letter from D. DeCicco to FDA re: ANDA# 211601/Sequence #0019 Tasimelteon Capsules, 20 mg	TEVA_TAS-000090177	TEVA_TAS-000090177		
163	12/2020	Package Outsert Side by Side Comparison	TEVA_TAS-000090341	TEVA_TAS-000090369		
164		S.2.1 Manufacturer	TEVA-TAS-000000132	TEVA-TAS-000000137		
165	7/25/2012	Licamele, Pleiomorphic Expression Of Non-24 Hour Disorder In The Totally Blind, Division Of Sleep Medicine, Department of Medicine, Brigham and Women's Hospital and Division of Sleep Medicine, Harvard Medical School, Boston, Ma	VNDHTLZ 00019810	VNDHTLZ 00019810		
166	6/13/2013	Tasimelteon Treatment Entrain The Circadian Clock And Demonstrates A Clinically Meaningful Benefit In Totally Blind Individuals With Non-24 Hour Circadian Rhythms	VNDHTLZ 00021131	VNDHTLZ 00021131		
167	4/18/2016	HETLIOZ Solutions™	VNDHTLZ 00026133	VNDHTLZ 00026149		
168	5/3/2012	Letter from R. Katz to M. Dressman re Meeting Denied	VNDHTLZ 00027710	VNDHTLZ 00027712		
169	6/1/2015	Summary of the risk management plan (RMP) for Hetlioz (tasimelteon)	VNDHTLZ 00028933	VNDHTLZ 00028939		
170	8/2016	HETLIOZ US Marketing	VNDHTLZ 00031311	VNDHTLZ 00031369		
171	6/10/2012	VEC-162 EOP2 Briefing Book	VNDHTLZ 00043085	VNDHTLZ 00043140		
172	10/7/2008	[REDACTED]	VNDHTLZ 01191737	VNDHTLZ 01191737		
173	3/27/2017	[REDACTED]	VNDHTLZ 00343584	VNDHTLZ 00343591		
174	11/29/2017	Intake to Dispense	VNDHTLZ 00345680	VNDHTLZ 00345703		
175	6/30/2018	[REDACTED]	VNDHTLZ 00346199	VNDHTLZ 00346201		
176	6/30/2018	[REDACTED]	VNDHTLZ 00346202	VNDHTLZ 00346204		

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177	10/8/2015	Prescription & Service Request Form	VNDHTLZ 00346229	VNDHTLZ 00346231		
178	6/30/2018	[REDACTED]	VNDHTLZ 00346232	VNDHTLZ 00346235		
179	1/22/2014	Vanda Pharmaceuticals, Presentation	VNDHTLZ 00376774	VNDHTLZ 00376809		
180	2013	[REDACTED]	VNDHTLZ 00379949	VNDHTLZ 00380014		
181	4/8/2014	It's Time to Treat Non-24,	VNDHTLZ 00380563	VNDHTLZ 00380571		
182	5/16/2013	Vanda Pharmaceuticals Inc. - NDA 205677 - 2.7.3 Summary of Clinical Efficacy	VNDHTLZ 00393771	VNDHTLZ 00393874		
183	5/13/2013	[REDACTED]	VNDHTLZ 00412860	VNDHTLZ 00413048		
184	10/4/2012	Clinical Study Report - Tasimelteon VP-VEC-162-1110 - An Open-Label, Single-Sequence Study to Assess the Effect of Multiple Doses of Tasimelteon on the Cytochrome P450 3A4 and 2C8 Enzymes Using Miazolam and Rosiglitazone as Substrates in Healthy Subjects	VNDHTLZ 00413794	VNDHTLZ 00414066		
185	4/4/2013	Clinical Trials, Tasimelteon VP-VEC-1112 An Open-Label, Single-Sequence Study in Two Cohorts of Healthy Subjects to Evaluate the Single-Dose Pharmacokinetics of Tasimelteon Alone and in Combination with a CYP3A4 Inducer, Rifampin	VNDHTLZ 00416825	VNDHTLZ 00417134		
186	3/18/2013	Clinical Study Report Amendment 2- VP-VEC-162-1101 - A Phase I, Open Label, Single-Center Study of the Absorption, Metabolism and Excretion of VEC-162 in Healthy Male	VNDHTLZ 00447639	VNDHTLZ 00447795		

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187	12/13/2012	Clinical Study Report - Tasimelteon VP-VEC-162-1111 - An Open-Label Single Sequence Study In Healthy Subjects To Evaluate The Single-Dose Pharmacokinetics of Tasimelteon Alone and In Combination With A CYP1A2 Inhibitor, Fluvoxamine	VNDHTLZ 00480469	VNDHTLZ 00480648		
188	8/19/2013	[REDACTED]	VNDHTLZ 00501479	VNDHTLZ 00501593		
189	4/29/2013	Clinical Study Report - Tasimelteon VP-VEC-162-3203- A Randomized Withdrawal Study to Demonstrate the Maintenance of Effect of 20 MG Tasimelteon in the Treatment of N24HSWD	VNDHTLZ 00525337	VNDHTLZ 00525871		
190	11/21/2013	Abbreviated Clinical Study Report - Tasimelteon - VP-VEC-162-2301 - Open-Label Extension Phase	VNDHTLZ 00534050	VNDHTLZ 00535237		
191	2015	Torres et al. <i>Absolute Bioavailability Of Tasimelteon</i> , American Journal Of Therapeutics 0, 1-6 (2015)	VNDHTLZ 00552043	VNDHTLZ 00552048		
192	12/12/2014	HETLIOZ® (tasimelteon) capsules 20 mg, Label	VNDHTLZ 00564640	VNDHTLZ 00564651		
193	12/2014	Hetlloz (Tasimelteon) Capsules 20 Mg, Label	VNDHTLZ 00564832	VNDHTLZ 00564843		
194	6/18/2019	Center For Drug Evaluation And Research Application Number 205677Orig1S000, Other Review(S)	VNDHTLZ 00569889	VNDHTLZ 00569992		
195	5/24/2012	Ninth Amendment to Amended and Restated License, Development and Commercialization Agreement between Vanda Pharmaceuticals Inc. and Bristol-Myers Squibb Company	VNDHTLZ 00937558	VNDHTLZ 00937559		

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196	4/25/2013	Tenth Amendment to Amended and Restated License, Development and Commercialization Agreement between Vanda Pharmaceuticals Inc. and Bristol-Myers Squibb Company	VNDHTLZ 00942365	VNDHTLZ 00942366		
197	1/11/2017	[REDACTED]	VNDHTLZ 00952508	VNDHTLZ 00952511		
198	1/12/2017	[REDACTED]	VNDHTLZ 00952513	VNDHTLZ 00952518		
199	12/2020	Vanda Presentation re Inventiveness of Method of Treatment Using Tasimelteon	VNDHTLZ 00959782	VNDHTLZ 00959786		
200	3/4/2010	Seventh Amendment to Amended and Restated License, Development and Commercialization Agreement between Vanda Pharmaceuticals Inc. and Bristol-Myers Squibb Company	VNDHTLZ 00977508	VNDHTLZ 00977509		
201	4/15/2010	Amendment to Amended and Restated License, Development and Commercialization Agreement between Vanda Pharmaceuticals Inc. and Bristol-Myers Squibb Company	VNDHTLZ 00977510	VNDHTLZ 00977513		
202	8/15/2004	Fax C. Clark to C. Spector-Dicks re Enclosing copy of Amendment to Amended and Restated License, Development and Commercialization Agreement between Vanda Pharmaceuticals Inc. and Bristol-Myers Squibb Company	VNDHTLZ 00982189	VNDHTLZ 00982242		
203	4/1/2014	Interim Clinical Study Report - Tasimelteon VP-VEC-162-3202 - Open-Label Safety of a 1-Year 20-MG Dose Regimen of Tasimelteon for the Treatment of Non-24-Hour Sleep-Wake Disorder (N24HSWD) in Blind Individuals with no Light Perception	VNDHTLZ 00997831	VNDHTLZ 00998495		
204	6/16/2011	[REDACTED]	VNDHTLZ 01001544	VNDHTLZ 01001545		
205	7/26/2011	[REDACTED]	VNDHTLZ 01001917	VNDHTLZ 01001933		

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206	8/3/2011	[REDACTED]	VNDHTLZ 01001934	VNDHTLZ 01001939		
207	8/15/2011	[REDACTED]	VNDHTLZ 01002117	VNDHTLZ 01002132		
208	8/15/2011	[REDACTED]	VNDHTLZ 01002133	VNDHTLZ 01002151		
209	8/16/2011	[REDACTED]	VNDHTLZ 01002152	VNDHTLZ 01002197		
210	8/18/2011	[REDACTED]	VNDHTLZ 01002218	VNDHTLZ 01002236		
211	8/22/2011	[REDACTED]	VNDHTLZ 01002237	VNDHTLZ 01002258		
212	9/16/2011	[REDACTED]	VNDHTLZ 01002572	VNDHTLZ 01002606		
213	11/28/2011	[REDACTED]	VNDHTLZ 01004923	VNDHTLZ 01004925		
214	2/4/2013	[REDACTED]	VNDHTLZ 01013476	VNDHTLZ 01013476		
215	10/18/2013	[REDACTED]	VNDHTLZ 01016243	VNDHTLZ 01016249		
216	12/5/2014	[REDACTED]	VNDHTLZ 01018456	VNDHTLZ 01018458		
217	3/30/2016	[REDACTED]	VNDHTLZ 01022574	VNDHTLZ 01022838		
218	8/6/2012	[REDACTED]	VNDHTLZ 01069852	VNDHTLZ 01069854		

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219	11/16/2012	[REDACTED]	VNDHTLZ 01072595	VNDHTLZ 01072596		
220	12/17/2012	[REDACTED]	VNDHTLZ 01072953	VNDHTLZ 01072956		
221	2/1/2013	[REDACTED]	VNDHTLZ 01074262	VNDHTLZ 01074319		
222	2/2/2013	[REDACTED]	VNDHTLZ 01074327	VNDHTLZ 01074328		
223	2/6/2013	[REDACTED]	VNDHTLZ 01074495	VNDHTLZ 01074542		
224	2/6/2013	[REDACTED]	VNDHTLZ 01074543	VNDHTLZ 01074590		
225	3/14/2013	[REDACTED] t	VNDHTLZ 01076890	VNDHTLZ 01076899		
226	3/20/2013	[REDACTED]	VNDHTLZ 01077431	VNDHTLZ 01077441		
227	7/29/2008	[REDACTED]	VNDHTLZ 01096014	VNDHTLZ 01096039		
228	4/6/2012	[REDACTED]	VNDHTLZ 01103603	VNDHTLZ 01103618		
229	1/23/2013	[REDACTED]	VNDHTLZ 01104268	VNDHTLZ 01104284		
230	1/24/2013	[REDACTED]	VNDHTLZ 01104347	VNDHTLZ 01104355		

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231	10/31/2011	[REDACTED]	VNDHTLZ 01185898	VNDHTLZ 01185917		
232	8/16/2011	[REDACTED]	VNDHTLZ 01187862	VNDHTLZ 01187907		
233	11/14/2013	Vanda Pharmaceuticals Inc. - Tasimelteon Advisory Committee Meeting Briefing Materials	VNDHTLZ 01194358	VNDHTLZ 01194474		
234	2/10/2014	Anatomy of the Circadian Timing System	VNDHTLZ 01194679	VNDHTLZ 01194680		
235	2/3/2014	Align 24 Non-24 Training Program Manual	VNDHTLZ 01194681	VNDHTLZ 01194706		
236	1/2014	Hetlioz (Tasimelteon) Capsules 20 Mg, Label	VNDHTLZ 01195398	VNDHTLZ 01195408		
237	6/25/1999	Czeisler, C. et al. <i>Stability, Precision And Near-24-Hour Period Of The Human Circadian Pacemaker</i> , Science 1999; 284: 2177-2181. Pmid: 10381883	VNDHTLZ 01205189	VNDHTLZ 01205194		
238	10/18/2013	Peripheral and Central Nervous System (PCNS) Drugs Advisory Committee - Tasimelteon (melatonin agonist)	VNDHTLZ 01207876	VNDHTLZ 01208078		
239	10/6/2016	Assuming at Buy: Fanapt and the Pipeline Getting in Rhythm with Hetlioz, Jefferies	VNDHTLZ 01211076	VNDHTLZ 01211118		
240	5/2/2017	1Q Earnings and Update, A Decent Quarter, PiperJaffray	VNDHTLZ 01212024	VNDHTLZ 01212031		
241	5/26/2017	Email from J. Kelly to C. Davis, et al. re: H.C. Wainwright / Vnda: The Little Engine That Could, Initiate With Buy and \$18 Target	VNDHTLZ 01212127	VNDHTLZ 01212129		
242	8/3/2017	2Q17 Update: Strong Quarter of Growth and Important Pipeline Catalysts Fast Approaching, JMP Securities with attachment	VNDHTLZ 01212182	VNDHTLZ 01212191		
243	4/30/2014	Survey, Hetlioz	VNDHTLZ 01212283	VNDHTLZ 01212287		
244	8/2/2017	Vanda Pharmaceuticals Inc. Form 10-Q	VNDHTLZ 01235136	VNDHTLZ 01235180		
245	10/17/2017	Vanda Pharmaceuticals Inc. Form 8-K	VNDHTLZ 01246806	VNDHTLZ 01246808		

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246	5/19/2004	Abbreviated Clinical Study Report - Melatonin Agonist - Effects of Single Doses of BMS-214778 on Daytime Sleep After Working a Night Shift in Healthy Subjects	VNDHTLZ 01320572	VNDHTLZ 01320585		
247	12/2014		VNDHTLZ 01667139	VNDHTLZ 01667253		
248	12/4/2013	Center for Drug Evaluation and Research - Application Number: 205677Orig1s000 - Clinical Pharmacology and Biopharmaceutics Review(s)	VNDHTLZ 01671581	VNDHTLZ 01671750		
249	3/13/2015	Vanda Pharmaceuticals Inc. Form 10-K	VNDHTLZ 01837328	VNDHTLZ 01837557		
250	6/3/2014	Vanda Pharmaceuticals Inc. Form 8-K	VNDHTLZ 01891346	VNDHTLZ 01891351		
251	6/4/2014	Vanda Pharmaceuticals Inc. Form 8-K	VNDHTLZ 01891446	VNDHTLZ 01891477		
252	8/7/2014	Vanda Pharmaceuticals Inc. Form 8-K	VNDHTLZ 01891963	VNDHTLZ 01891972		
253	10/27/2014	Vanda Pharmaceuticals Inc. Form 8-K	VNDHTLZ 01892194	VNDHTLZ 01892202		
254	10/28/2014	Vanda Pharmaceuticals Inc. Form 8-K	VNDHTLZ 01892364	VNDHTLZ 01892368		
255	1/10/2014	Vanda Pharmaceuticals Inc. 2014 Corporate Presentation	VNDHTLZ 01894110	VNDHTLZ 01894140		
256	6/10/2014	New Hetlioz Patent Could be Transformative, PiperJaffray	VNDHTLZ 01895129	VNDHTLZ 01895131		
257	10/7/1997	Bristol-Myers Squibb Pharmaceutical Research Institute Scientific Report	VNDHTLZ 01904832	VNDHTLZ 01904845		
258	3/13/2014	Raising Estimates and Price Target on Confirmed Hetlioz Pricing, JMP Securities	VNDHTLZ 01905619	VNDHTLZ 01905624		
259	3/13/2014	Hetlioz Price Now Listed, Vnda Remains a Top Pick, PiperJaffray	VNDHTLZ 01905625	VNDHTLZ 01905627		
260	6/30/2009	Sixth Amendment to Amended and Restated License, Development and Commercialization Agreement between Vanda Pharmaceuticals Inc. and Bristol-Myers Squibb Company	VNDHTLZ 01912296	VNDHTLZ 01912297		

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261	10/23/2003	[REDACTED]	VNDHTLZ 01912328	VNDHTLZ 01912381		
262	2012	Paulis, <i>Cardiovascular Effects Of Melatonin Receptor Agonists</i> , Informa, Uk. Ltd Issn 1354-3784	VNDHTLZ 01920336	VNDHTLZ 01920353		
263	11/14/2013	Transcript of Speaker ID FDA - FDDVDS.com	VNDHTLZ 01937275	VNDHTLZ 01937353		
264	8/5/2015	Email from M. Dressman to S. Morris re Lancet Publication	VNDHTLZ 01955485	VNDHTLZ 019554997		
265	2005	Circadian Rhythm Sleep Disorders, American Academy of Sleep Medicine	VNDHTLZ 01976176	VNDHTLZ 01976180		
266	12/8/2009	Zee et al. <i>Effects Of Ramelteon On Insomnia Symptoms Induced By Rapid Eastward Travel</i> , Sleep Medicine 11: (2010) 525-533	VNDHTLZ 01986899	VNDHTLZ 01986907		
267	8/28/2013	Email from M. Dressman to J. Hamilton re: Abstracts/Posters	VNDHTLZ 02021365	VNDHTLZ 02021365		
268	8/11/2004	Email from [REDACTED] to C. Clark re Clinical Study Reports for [REDACTED]	VNDHTLZ 02059430	VNDHTLZ 02059430		
269	4/9/2013	[REDACTED]	VNDHTLZ 02077792	VNDHTLZ 02077795		
270	5/26/2015	Press Release - PRNewswire - Vanda Receives Innovation Award from the National Organization for Rare Disorders for Development of HETLIOZ®	VNDHTLZ 02152095	VNDHTLZ 02152097		
271	11/4/2015	Guidance Reiterated with Continued Hetlioz Growth, JMP Securitie	VNDHTLZ 02159464	VNDHTLZ 02159470		
272	11/3/2015	Vanda Pharmaceuticals Inc. Form 8-K	VNDHTLZ 02162181	VNDHTLZ 02162193		
273	11/4/2015	Vanda Pharmaceuticals Inc. From 10-Q for Quarter Ended September 30, 2015	VNDHTLZ 02162294	VNDHTLZ 02162393		
274	9/15/2017	2017 Sept. Forecast	VNDHTLZ 02163887	VNDHTLZ 02163913		

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275	5/22/2018	Hetlioz Sales Growth Leads Upside Opportunities; Buy, \$26 TP, Citi Research	VNDHTLZ 02169358	VNDHTLZ 02169401		
276	5/3/2018	1Q18 Results a Win as Vanda Continues to Fire on all Cylinders, JMP Securities	VNDHTLZ 02169641	VNDHTLZ 02169647		
277	2006	Wyatt et al., Sleep-Facilitating Effect Of Exogenous Melatonin In Healthy Young Men And Women Is Circadian-Phase Dependent, 29 Sleep 609, 615-16 (2006)	VNDHTLZ 02172465	VNDHTLZ 02172474		
278	12/14/2007	Third Amendment to Amended and Restated License, Development and Commercialization Agreement between Vanda Pharmaceuticals Inc. and Bristol-Myers Squibb Company	VNDHTLZ 02198007	VNDHTLZ 02198008		
279	5/2/2008	Fourth Amendment to Amended and Restated License, Development and Commercialization Agreement between Vanda Pharmaceuticals Inc. and Bristol-Myers Squibb Company	VNDHTLZ 02198009	VNDHTLZ 02198010		
280	9/19/2008	Fifth Amendment to Amended and Restated License, Development and Commercialization Agreement between Vanda Pharmaceuticals Inc. and Bristol-Myers Squibb Company	VNDHTLZ 02198011	VNDHTLZ 02198012		
281	9/5/2016	Email from A. Williams to G. Reverberi et al. re Melatonin Literature Review Findings	VNDHTLZ 02213489	VNDHTLZ 02213489		
282	1/29/1990	Folkard et al. <i>Melatonin Stabilises Sleep Onset Time in a Blind Man without Entrainment of Cortisol or Temperature Rhythms</i> , Neuroscience Letters, 113 (1990)	VNDHTLZ 02213518	VNDHTLZ 02213523		
283	1991	Sack et al. <i>Melatonin Administration to Blind People: Phase Advances and Entrainment</i> , 6 J. Biol. Rhythms 249, 252-56 (1991)	VNDHTLZ 02213550	VNDHTLZ 02213583		
284	5/3/2018	Email from L. Hamilton to G. Reverberi re Hetlioz Modules with attachments	VNDHTLZ 02223145	VNDHTLZ 02223145		
285	9/25/2015	Email from L. Wenograd to M. Shapiro re Hetlioz Consumer Deck with attachments	VNDHTLZ 02301807	VNDHTLZ 02301807		

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286	2013	Emens et al. <i>Non-24-Hour Disorder In Blind Individuals Revisited: Variability And The Influence Of Environmental Time Cues</i> , 36 Sleep 1091 (2013)	VNDHTLZ 02301828	VNDHTLZ 02301837		
287	7/30/2004	VEC-162 Clinical Trial Summaries	VNDHTLZ 02363515	VNDHTLZ 02363530		
288	4/13/2017	M. Polymeropoulos Declaration under 37 CFR 1.132	VNDHTLZ 02460579	VNDHTLZ 02460590		
289	3/1/2007	Second Amendment to Amended and Restated License, Development and Commercialization Agreement between Vanda Pharmaceuticals Inc. and Bristol-Myers Squibb Company	VNDHTLZ 02472736	VNDHTLZ 02472737		
290	11/26/2003	New Research Plan	VNDHTLZ 02474271	VNDHTLZ 02474286		
291	2008	Arendt, J., And Shantha Rajaratnam, <i>Melatonin and Its Agonists: An Updat</i> , The British Journal of Psychiatry. 2008 Oct; 193(4):267-9	VNDHTLZ 02481943	VNDHTLZ 02481946		
292	10/21/2015	Commercial Stage CNS Company; Initiate with BUY and \$20 TP, Brean Capital	VNDHTLZ 02491369	VNDHTLZ 02491387		
293	7/29/2015	Vanda Pharmaceuticals Inc. Form 10-Q for Quarter Ended June 30, 2015	VNDHTLZ 02493912	VNDHTLZ 02493953		

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294	5/5/2016	Vanda Pharmaceuticals Inc. Form 10-Q for Quarter Ended March 31, 2016	VNDHTLZ 02494691	VNDHTLZ 02494727		
295	5/3/2017	Vanda Pharmaceuticals Inc. Form 10-Q for Quarter Ended March 31, 2017	VNDHTLZ 02495349	VNDHTLZ 02495387		
296	2/15/2018	Vanda Pharmaceuticals Inc. Form 10-K for Fiscal Year Ended December 31, 2017	VNDHTLZ 02495489	VNDHTLZ 02495591		
297	2008	Richardson et al, <i>Circadian Phase-Shifting Effects of Repeated Ramelteon Administration in Healthy Adults</i> , Journal of Clinical Sleep Medicine, Vol. 4 No. 5, 2008	VNDHTLZ 02584772	VNDHTLZ 02584777		
298	1998	Lewy et al. <i>The Human Phase Response Curve (Prc) To Melatonin Is About 12 Hours Out Of Phase With The Prc To Light</i> , 15 Chronobiology International 71 (1998)	VNDHTLZ 02587702	VNDHTLZ 02587714		
299	8/26/2013	Email From J. Wang To N. Platt Re F199 Coa & Spec Change History	VNDHTLZ 02637385	VNDHTLZ 02637577		
300		Presentation, RESET STUDY, VP-VEC-162-3203	VNDHTLZ 02683574	VNDHTLZ 02683589		
301	11/4/2016	Vanda Pharmaceuticals Inc. Form 10-Q for Quarter Ended September 30, 2016 (Redacted)	VNDHTLZ 02687616	VNDHTLZ 02687656		
302	2/17/2017	Vanda Pharmaceuticals Inc. Form 10-K for Fiscal Year Ended December 31, 2016	VNDHTLZ 02687847	VNDHTLZ 02687990		

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303	1/5/1995	Czeisler et al. <i>Suppression Of Melatonin Secretion In Some Blind Patient By Exposure To Bright Light</i> , NEJM (1995).	VNDHTLZ 02688213	VNDHTLZ2688218		
304	2/12/2016	Vanda Pharmaceuticals Inc. From 10-K for Fiscal Year Ended December 31, 2015	VNDHTLZ 02691308	VNDHTLZ 02691442		
305	5/7/2014	Vanda Pharmaceuticals Inc. Form 10-Q	VNDHTLZ 02781372	VNDHTLZ 02781478		
306	8/8/2014	Vanda Pharmaceuticals Inc. From 10-Q for Quarter Ended June 30, 2014	VNDHTLZ 02781479	VNDHTLZ 02781535		
307	10/27/2014	Vanda Pharmaceuticals Inc. From 10-Q for Quarter Ended September 30, 2014	VNDHTLZ 02781536	VNDHTLZ 02781597		
308	2/2/2010	Antidepressant And Anxiolytic Activity Of Tasimelteon (Vec-162) In Rodent Models	VNDHTLZ 02802951	VNDHTLZ 02802963		
309	7/30/2015	Reports 2Q: Posts Strong Fanapt Sales and Steady Growth of Hetlioz, Jefferies	VNDHTLZ 02833440	VNDHTLZ 02833445		
310	7/30/2015	Vanda Reports Better than Expected 2Q15 Fanapt Sales, JMP Securities	VNDHTLZ 02833446	VNDHTLZ 02833451		
311	6/29/2017	Sales force Update	VNDHTLZ 02835733	VNDHTLZ 02835733		
312	1/8/2018	In-Line 2018 Guide with Hetlioz Growth Expected & Fanapt Still a Show-Me Story, Jefferies	VNDHTLZ 02836020	VNDHTLZ 02836025		
313	1/7/2018	Solid 4Q17 Performance and 2018 Guidance Doesn't Disappoint, JMP Securities	VNDHTLZ 02836032	VNDHTLZ 02836037		
314	4/25/2013	[REDACTED]	VNDHTLZ 02838084	VNDHTLZ 02838086		
315	5/9/2013	Vanda Cuts Expenses in 1Q as it Prepares for New Drug Application Submission for Tasimelteon, Morningstar	VNDHTLZ 02838097	VNDHTLZ 02838101		
316	8/2/2018	Q2: Hetlioz Does Not Disappoint; Fanapt Steady; Two Ph. II Read-Outs Late 2018, Jefferies	VNDHTLZ 02840265	VNDHTLZ 02840274		

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317	11/2/2017	Vanda Pharmaceuticals Inc. Form 10-Q	VNDHTLZ 02852864	VNDHTLZ 02852908		
318	6/2004	Licensing Opportunity June 2004	VNDHTLZ 02853883	VNDHTLZ 02853896		
319	5/5/2016	A Modest Beat; Reiterate BUY and \$20 TP, Brean Capital	VNDHTLZ 02865843	VNDHTLZ 02865846		
320	4/4/2018	Spreadsheet - Tasimelteon N24HSWD US Market Assumptions	VNDHTLZ 02909091	VNDHTLZ 02909091		
321	12/14/2017	Sample Appeal Letter	VNDHTLZ 02927384	VNDHTLZ 02927388		
322	11/1/2013	Vanda's 4Q Results a Bit Soft; Hetlioz Launch in 2Q is Key Focus, Morningstar	VNDHTLZ 02928939	VNDHTLZ 02928957		
323	10/21/2015	Commercial Stage CNS Company; Initiate with BUY and \$20 TP, Brean Capital, October 21, 2015	VNDHTLZ 02929034	VNDHTLZ 02929052		
324	11/4/2015	Vanda Reports Ongoing Hetlioz Launch Progress; Maintaining Fair Value Estimate, Morningstar	VNDHTLZ 02929060	VNDHTLZ 02929067		
325	2/20/2015	Vanda's Hetlioz Launch Slower than Expected; Maintaining Fair Value Estimate, Morningstar	VNDHTLZ 02929076	VNDHTLZ 02929082		
326	10/6/2016	Assuming at Buy: Fanapt and the Pipeline Getting in Rhythm with Hetlioz, Jefferies	VNDHTLZ 02929099	VNDHTLZ 02929141		
327	3/5/2018	JET8-Real Efficacy Measures Cut Through Our Sleep-Deprived Cloudiness, PiperJaffray	VNDHTLZ 02929384	VNDHTLZ 02929389		
328	6/13/2012	Vanda Pharma: Trading Below Cash with Upcoming Catalysts Expected 2H12, Seeking Alpha	VNDHTLZ 02929833	VNDHTLZ 02929835		
329	8/2/2011	Email From Yc To N. Platt Re Discussion On The Sample Concentration In The Assay And Rs Method	VNDHTLZ 02954202	VNDHTLZ 02954221		
330	6/20/2012	[REDACTED]	VNDHTLZ 02954587	VNDHTLZ 02954596		

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331	4/25/2011	[REDACTED]	VNDHTLZ 02961350	VNDHTLZ 02961351		
332	11/9/2010	[REDACTED]	VNDHTLZ 02962650	VNDHTLZ 02962655		
333	1/30/2013	[REDACTED]	VNDHTLZ 02970297	VNDHTLZ 02970303		
334	5/3/2007	Email from C. Hill to A. Bahiman re All Kinds of Documents	VNDHTLZ 02972945	VNDHTLZ 02973008		
335	5/19/2015	Spreadsheet - Fanapt - Global	VNDHTLZ 02995660	VNDHTLZ 02995660		
336	8/8/2013	Tasimelteon Independent Market Opportunity Validation, Final Results Discussion,	VNDHTLZ 02997405	VNDHTLZ 02997449		
337	8/1/2018	Q2 Update: Sometimes Simple is Good; Raising Target to \$26, Seaport Global	VNDHTLZ 02997998	VNDHTLZ 02998003		
338	8/2/2018	2Q18 Results Demonstrate Good Execution for Hetlioz, Fanapt and the Pipeline, JMP Securities	VNDHTLZ 02998005	VNDHTLZ 02998011		
339	8/2/2018	Keep Your Eyes on VNDA: Multiple Near-Term Catalysts, Oppenheimer	VNDHTLZ 02998013	VNDHTLZ 02998020		
340	1999	Spitzer et al. <i>Jet Lag: Clinical Features, Validation Of A New Syndrome-Specific Scale, And Lack Of Response To Melatonin In A Randomized, Double-Blind Trial</i> , Am. J. Psych. (1999)	VNDHTLZ 03009660	VNDHTLZ 03009664		
341	5/8/2014	1Q: High Spend, but for a Worthy-Cause, Weakness Overdone, PiperJaffray	VNDHTLZ 03017963	VNDHTLZ 03017971		

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342	4/4/2011	Crewe et al. <i>Are There Differences In The Catalytic Activity Per Unit Enzyme Of Recombinantly Expressed And Human Liver Microsomal Cytochrome P450 2C9?</i> A Systematic Investigation Into Inter-System Extrapolation Factors, 32 <i>Biopharmaceutics & Drug Disposition</i> 303	VNDHTLZ 03056346	VNDHTLZ 03056361		
343	10/2003	Hack, L., et al. The Effects Of Low-Dose 0.5-Mg Melatonin On The Free-Running Circadian Rhythms Of Blind Subjects, <i>Journal Of Biological Rhythms</i> , Vol. 18 No. 5, October 2003	VNDHTLZ 03063922	VNDHTLZ 03063931		
344	5/6/2015	Vanda Pharmaceuticals Inc. Form 10-Q	VNDHTLZ 03079908	VNDHTLZ 03079948		
345	8/4/2015	Vanda Pharmaceuticals Inc. Form 10-Q	VNDHTLZ 03079949	VNDHTLZ 03080020		
346	5/4/2016	Vanda Pharmaceuticals Inc. Form 10-Q	VNDHTLZ 03080021	VNDHTLZ 03080055		
347	11/3/2013	Vanda Pharmaceuticals Inc. Form 10-Q	VNDHTLZ 03080056	VNDHTLZ 03080095		
348	2/15/2018	Vanda Pharmaceuticals Inc. Form 10-K	VNDHTLZ 03080096	VNDHTLZ 03080204		
349	5/3/2017	Vanda Pharmaceuticals Inc. Form 10-Q	VNDHTLZ 03080205	VNDHTLZ 03080243		
350	5/2/2018	Vanda Pharmaceuticals Inc. Form 10-Q	VNDHTLZ 03080355	VNDHTLZ 03080423		
351	8/1/2018	Vanda Pharmaceuticals Inc. Form 10-Q	VNDHTLZ 03080424	VNDHTLZ 03080463		
352	10/31/2018	Vanda Pharmaceuticals Inc. Form 10-Q	VNDHTLZ 03080464	VNDHTLZ 03080513		
353	5/1/2019	Vanda Pharmaceuticals Inc. Form 10-Q	VNDHTLZ 03080514	VNDHTLZ 03080559		
354	7/31/2019	Vanda Pharmaceuticals Inc. Form 10-Q	VNDHTLZ 03080560	VNDHTLZ 03080607		
355	10/31/2019	Vanda Pharmaceuticals Inc. Form 10-Q	VNDHTLZ 03080608	VNDHTLZ 03080675		

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356		Spreadsheet - [REDACTED]	VNDHTLZ 03081570	VNDHTLZ 03081570		
357	1965	Snyder, S., et al, <i>Control of the Circadian Rhythm in Serotonin Content of the Rat Pineal Gland</i> , Physiology, Vol. 53 1965	VNDHTLZ 03082524	VNDHTLZ 03082528		
358	1977	Miles, et al. <i>Blind Man Living In Normal Society Has Circadian Rhythms Of 24.9 Hours</i> , Science 421 (1977)	VNDHTLZ 03082536	VNDHTLZ 03082539		
359	1978	Lynch, H., et al., <i>Entrainment of Rhythmic Melatonin Secretion in Man to a 12-Hour Phase Shift in the Light/Dark Cycle</i> , Life Sciences, Vol. 23 1978	VNDHTLZ 03082540	VNDHTLZ 03082546		
360	9/1/1999	Spitzer, Robert, et al., <i>Jet Lag: Clinical Features, Validation of a New Syndrome-Specific Scale, and Lack of Response to Melatonin in a Randomized, Double-Blind Trial</i> , Am J Psychiatry 1999	VNDHTLZ 03082597	VNDHTLZ 03082601		
361	2/2002	Sharkey And Eastman, <i>Melatonin Phase Shifts Human Circadian Rhythms In A Placebo-Controlled Simulated Night-Work Study</i> , 282 American Journal Of Physiology-Regulatory, Integrative And Comparative Physiology. R454 (2002)	VNDHTLZ 03082644	VNDHTLZ 03082665		
362	2003	Lewy et al. <i>Zeitgeber Hierarchy In Humans: Resetting The Circadian Phase Positions Of Blind People Using Melatonin</i> , 20 Chronobiology International 837 (2003)	VNDHTLZ 03082681	VNDHTLZ 03082698		
363	2/2004	Hack, <i>Thesis On Melatonin And Free-Running Circadian Rhythms In The Blind Proquest</i> (2004)	VNDHTLZ 03082707	VNDHTLZ 03082877		
364		American Academy of Sleep Medicine, International Classification of Sleep Disorders (ICSD) II (2005)	VNDHTLZ 03082878	VNDHTLZ 03083101		

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365	2/2005	Hirai et al. <i>Ramelteon (Tak-375) Accelerates Reentrainment Of Circadian Rhythm After A Phase Advance Of The Light-Dark Cycle In Rats</i> , 20 <i>Journal Of Biological Rhythms</i> 27 (2005)	VNDHTLZ 03083102	VNDHTLZ 03083112		
366	5/14/2007	Gronfier et al. <i>Entrainment Of The Human Circadian Pacemaker To Longer-Than-24-H Days</i> , 104 <i>Phas</i> 9081 (2007)	VNDHTLZ 03083133	VNDHTLZ 03083139		
367	3/23/2006	Pandi-Perumal et al. <i>Dim Light Melatonin Onset (Dlmo): A Tool For The Analysis Of Circadian Phase I Human Sleep And Chronobiological Disorders</i> , 31 <i>Progress In Neuro-Psychopharmacology & Biological Psychiatry</i> 1 (2007)	VNDHTLZ 03083140	VNDHTLZ 03083150		
368	8/26/2008	Burgess, H., <i>Individual Differences in the Amount and Timing of Salivary Melatonin Secretion</i> , <i>PLoS ONE</i> 3(8): 2008	VNDHTLZ 03083151	VNDHTLZ 03083159		
369	2008	Knight, <i>Systematic Reviews Of Animal Experiments Demonstrate Poor Contributions Toward Human Healthcare</i> , 3 <i>Reviews On Recent Clinical Trials</i> 89 (2008)	VNDHTLZ 03083170	VNDHTLZ 030831777		
370	4/2009	Emens et al. <i>Phase Angle Of Entrainment In Morning-And-Evening Types Under Naturalistic Conditions</i> , 313 <i>Neuroscience Letters</i> 158 (2001)	VNDHTLZ 03083203	VNDHTLZ 03083218		
371	12/2010	Dodson And Zee, <i>Therapeutics For Circadian Rhythm Sleep Disorders</i> , <i>Sleep Medicine Clinics</i> 701 (2010)	VNDHTLZ 03083241	VNDHTLZ 03083260		
372	3/2010	Van Der Worp et al. <i>Can Animal Models Of Disease Reliably Inform Human Studies ?</i> 7 <i>Plos Medicine</i> E1000245 (2010)	VNDHTLZ 03083301	VNDHTLZ 03083308		
373	2/2011	Arrowsmith, <i>Phase III And Submission Failures: 2007-2010</i> , 10 <i>Nature Reviews Drug Discovery</i> 1	VNDHTLZ 03083309	VNDHTLZ 03083309		

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374	2011	Duffy, J., et al., <i>Sex difference in the near-24-hour intrinsic period of the human circadian timing system</i> , PNAS 2011	VNDHTLZ 03083310	VNDHTLZ 03083316		
375	3/12/2011	Jones et al. <i>Animal Models Of Schizophrenia</i> , British Journal Of Pharmacology (2011)	VNDHTLZ 03083317	VNDHTLZ 03083349		
376	3/2014	Adams, <i>Melatonin Agonists In The Management Of Sleep Disorders: A Focus On Ramelteon And Tasimelteon</i> , Mental Health Clinician (2014)	VNDHTLZ 03083379	VNDHTLZ 03083384		
377	8/27/2014	Denayer et al. <i>Animal Models In Translational Medicine: Validation And Prediction</i> , New Horizons In Translation Medicine (2014)	VNDHTLZ 03083385	VNDHTLZ 03083391		
378	2014	Johnsa And Neville, <i>Tasimelteon: A Melatonin Receptor Agonist For Non-24-Hour Sleep-Wake Disorder</i> , 48 Annals Of Pharmacotherapy 1636 (2014)	VNDHTLZ 03083392	VNDHTLZ 03083397		
379	7/7/1905	Auger, R., et al., <i>Clinical Practice Guideline for the Treatment of Intrinsic Circadian Rhythm Sleep-Wake Disorders: Advanced SleepWake Phase Disorder (ASWPD), Delayed Sleep-Wake Phase Disorder (DSWPD), Non-24-Hour Sleep-Wake Rhythm Disorder (N24SWD), and Irregular Sleep-Wake Rhythm Disorder (ISWRD). An Update for 2015</i> , Journal of Clinical Sleep Medicine, Vol. 11, No. 10, 2015	VNDHTLZ 03083398	VNDHTLZ 03083435		
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383	5/2016	Williams et al. Comparative Review Of Approved Melatonin Agonists For The Treatment Of Circadian Rhythm Sleep-Wake Disorders, 36 Pharmacotherapy 1028 (2016)	VNDHTLZ 03083542	VNDHTLZ 03083555		
384	6/12/2017	Phillips, A., et al., <i>Irregular sleep/wake patterns are associated with poorer academic performance and delayed circadian and sleep/wake timing</i> , Scientific Reports 2017	VNDHTLZ 03083570	VNDHTLZ 03083582		
385	2018	Burgess And Emens, Drugs Used In Circadian Sleep-Wake Rhythm Disturbances, 13 Sleep Medicine Clinics, 231 (2018)	VNDHTLZ 03083613	VNDHTLZ 03083623		
386	7/15/2018	Watanabe et al. A Case Of Non-24-Hour Sleep-Wake Rhythm Disorder Treated With A Low Dose Of Ramelteon And Behavioral Education, 14 Journal Of Clinical Sleep Medicine 1265 (2018)	VNDHTLZ 03083659	VNDHTLZ 03083661		
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388	7/1/2013	McDonnell And Dang, <i>Basic Review Of The Cytochrome P450 System</i> , 4 Journal Of The Advanced Practitioner In Oncology 263	VNDHTLZ 03083831	VNDHTLZ 03083839		
389	1/2002	Offord, <i>The Importance Of A Wide Therapeutic Window: Fexofenadine Is Safe And Effective Over A Broad Range Of Plasma Concentrations</i> , 109 Journal Of Allergy And Clinical Immunology S106	VNDHTLZ 03083840	VNDHTLZ 0308340		
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391	3/28/2016	Almond et al. <i>Prediction Of Drug-Drug Interactions Arising From Cyp3A Induction Using A Physiologically Based Dynamic Model</i> , 44 Drug Metabolism And Disposition 821	VNDHTLZ 03083871	VNDHTLZ 03083914		
392	2009	Benet, <i>The Drug Transporter-Metabolism Alliance: Uncovering And Defining The Interplay</i> , 6 Molecular Pharmaceutics 1631	VNDHTLZ 03083915	VNDHTLZ 03083915		
393	1986	Blyden et al. <i>Ketoconazole Does Not Impair Antipyrine Clearance In Humans</i> , 24 International Journal Of Clinical Pharmacology, Therapy And Toxicology 225	VNDHTLZ 03083938	VNDHTLZ 03083939		
394	6/1996	Engel et al. <i>Antipyrine As A Probe For Human Oxidative Drug Metabolism: Identification Of The Cytochrome P450 Enzymes Catalyzing 4-Hydroxyantipyrine, 3-Hydroxymethylantipyrine, And Norantipyrine Formation</i> , 59 Clinical Pharmacology & Therapeutics 613	VNDHTLZ 03083962	VNDHTLZ 03083972		
395	10/15/2007	Foti And Wahlstrom, <i>Cyp2C19 Inhibition: The Impact Of Substrate Probe Selection On In Vitro Inhibition Profiles</i> , 16 Pharmacokinetics And Drug Metabolism 523	VNDHTLZ 03083973	VNDHTLZ 03083978		
396	3/4/2010	Foti et al. <i>Selection Of Alternative Cyp3A4 Probe Substrates For Clinical Drug Interaction Studies Using In Vitro Data And In Vivo Simulation</i> , 16 Drug Metabolism & Disposition 961	VNDHTLZ 03083979	VNDHTLZ 03083985		
397	2004	Ghosal et al. <i>Identification Of Human Udp-Glucuronosyltransferase Enzyme(S) Responsible For The Glucuronidation Of 3-Hydroxydesloratadine</i> , 25 Biopharmaceutics & Drug Disposition 243	VNDHTLZ 03083986	VNDHTLZ 03083995		
398	8/6/2009	Ghosal et al. <i>Metabolism Of Loratadine And Further Characterization Of Its In Vitro Metabolites</i> , 3 Drug Metabolism 162	VNDHTLZ 03083996	VNDHTLZ 03084004		

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400	3/22/2006	Klotz, Clinical Impact Of Cyp2C19 Polymorphism On The Action Of Proton Pump Inhibitors: A Review Of A Special Problem, 44 International Journal Of Clinical Pharmacology And Therapeutics 297 (2006)	VNDHTLZ 03084036	VNDHTLZ 03084041		
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402	2019	Parkinson et al. System-Dependent Outcomes During The Evaluation Of Drug Candidates As Inhibitors Of Cytochrome P450 (Cyp) And Uridine Diphosphate Glucuronosyltransferase (Ugt) Enzymes: Human Hepatocytes Versus Liver Microsomes Versus Recombinant Enzymes, 25 Drug Metabolism And Pharmacokinetics 16	VNDHTLZ 03084059	VNDHTLZ 03084070		
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404	1999	Rodrigues, Integrated Cytochrome P450 Reaction Phenotyping: Attempting To Bridge The Gap Between Cdna-Expressed Cytochrome P450 And Native Liver Microsomes, 57 Biochemical Pharmacology 465	VNDHTLZ 03084291	VNDHTLZ 03084306		
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406	6/19/2000	Venkatakrishnan et al. Comparison Between Cytochrome P450 (Cyp) Content And Relative Activity Approaches To Scaling From Cdna-Expressed Cyps To Human Liver Microsomes: Ratios Of Accessory Proteins As Sources Of Discrepancies Between The Approaches, 28 Drug Metabolism And Disposition 1493	VNDHTLZ 03084315	VNDHTLZ 03084326		
407	9/21/2006	Wang, Cyp4F Enzymes Are The Major Enzymes In Human Liver Microsomes That Catalyze The O-Demethylation Of The Antiparasitic Prodrug Db289, 34 Drug Metabolism And Disposition	VNDHTLZ 03084327	VNDHTLZ 03084336		
408	1989	Wilkinson et al. Genetic Polymorphism Of S-Mephenytoin Hydroxylation, 43 Pharmacology And Therapeutics 53	VNDHTLZ 03084337	VNDHTLZ 03084360		
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420	2017	Friedman, Y., Where Are Drugs Invented, and Why Does It Matter? ACS Medicinal Chemistry Letters, 8(6), pp. 589–591,	VNDHTLZ 03084590	VNDHTLZ 03084592		
421	7/1993	Grabowski, H. and J. Vernon, (1994) Returns to R&D on new drug introductions in the 1980s, Journal of Health Economics, 13(4)	VNDHTLZ 03084593	VNDHTLZ 03084616		
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430	2014	Petrova E., <i>Innovation in the Pharmaceutical Industry: The Process of Drug Discovery and Development</i> , Innovation and Marketing in the Pharmaceutical Industry, International Series in Quantitative Marketing, 2014, M. Ding, J. Eliashberg, and S. Stremersch (Eds.), New York, NY: Springer, pp. 54–56	VNDHTLZ 03084784	VNDHTLZ 03084847		
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433	11/2007	Venkataraman, S. and S. Stremersch, (2007) <i>The Debate on Influencing Doctors' Decisions: Are Drug Characteristics the Missing Link?</i> Management Science, 53(11), pp. 1688–1701,	VNDHTLZ 03084868	VNDHTLZ 03084881		
434	7/2018	FDA, Indications and Usage Section of Labeling for Human Prescription Drug and Biological Products — Content and Format: Guidance for Industry,	VNDHTLZ 03084882	VNDHTLZ 03084901		
435	1/31/2014	FDA, Hetlioz Approval Letter	VNDHTLZ 03084902	VNDHTLZ 03084909		
436	1/2014	FDA, Hetlioz Label	VNDHTLZ 03084910	VNDHTLZ 03084920		
437	1/31/2014	FDA, Hetlioz NDA Acceptance Letter	VNDHTLZ 03084921	VNDHTLZ 03084925		
438	12/31/2019	FDA, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, 40th edition	VNDHTLZ 03084926	VNDHTLZ 03086551		
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441	6/2009	Emerging Health Care Issues: Follow-on Biologic Drug Competition, Federal Trade Commission	VNDHTLZ 03086860	VNDHTLZ 03086979		
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444		Abbreviated New Drug Application (ANDA): Generics, FDA	VNDHTLZ 03087039	VNDHTLZ 03087042		
445		About Non-24, Hetlioz, available at https://hetlioz.com/aboutnon	VNDHTLZ 03087043	VNDHTLZ 03087046		
446	10/23/2013	Cephalon Sues Eagle Over Plans for Liquid Treanda, Law360	VNDHTLZ 03087047	VNDHTLZ 03087048		
447	10/16/2014	Efficacy and Safety of Tasimelteon Compared with Placebo in Totally Blind Subjects with Non-24-Hour Sleep-Wake Disorder, Vanda Pharmaceuticals, Identification No. NCT01163032	VNDHTLZ 03087049	VNDHTLZ 03087057		
448		Getting Medicare if You Have a Disability, Medicare,	VNDHTLZ 03087058	VNDHTLZ 03087059		
449	8/11/2015	Hetlioz Pill May Ease Sleep Disorder for Some Blind People, Reuter	VNDHTLZ 03087060	VNDHTLZ 03087068		
450	1/2020	If You're Blind or Have Low Vision — How We Can Help, Social Security Administration	VNDHTLZ 03087069	VNDHTLZ 03087084		
451		Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, FDA	VNDHTLZ 03087085	VNDHTLZ 03087085		
452		Reviewing the Disability Employment Research on People who are Blind or Visually Impaired: Key Takeaways, American Foundation for the Blind	VNDHTLZ 03087086	VNDHTLZ 03087095		
453		Step 4: FDA Drug Review, FDA	VNDHTLZ 03087096	VNDHTLZ 03087097		
454		Taking HETLIOZ® (tasimelteon), Hetlioz	VNDHTLZ 03087098	VNDHTLZ 03087100		
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456		The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective, FDA, http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm	VNDHTLZ 03087107	VNDHTLZ 03087110		

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458	2/28/2020	Biovail Corporation 2005 Annual Report	VNDHTLZ 03087113	VNDHTLZ 03087207		
459	2/27/2009	Biovail Corporation Form 20-F	VNDHTLZ 03087208	VNDHTLZ 03087566		
460	12/22/2014	Eagle Pharmaceuticals, Inc. Form 10-K	VNDHTLZ 03087567	VNDHTLZ 03087676		
461	2/28/2019	Eagle Pharmaceuticals, Inc. Form 10-K	VNDHTLZ 03087677	VNDHTLZ 03087894		
462	3/26/1998	Sepracor Inc. Form 10-K	VNDHTLZ 03087895	VNDHTLZ 03088160		
463	3/27/2001	Sepracor Inc. Form 10-K	VNDHTLZ 03088161	VNDHTLZ 03088180		
464	3/29/2002	Sepracor Inc. Form 10-K	VNDHTLZ 03088181	VNDHTLZ 03088248		
465	3/12/2004	Sepracor Inc. Form 10-K	VNDHTLZ 03088249	VNDHTLZ 03088274		
466	3/12/2004	Sepracor Inc. Form 10-K	VNDHTLZ 03088275	VNDHTLZ 03088326		
467	3/16/2006	Sepracor Inc. Form 10-K	VNDHTLZ 03088327	VNDHTLZ 03088377		
468	3/16/2006	Sepracor Inc. Form 10-K	VNDHTLZ 03088378	VNDHTLZ 03088443		
469	3/16/2007	Vanda Pharmaceuticals Inc. Form 10-K	VNDHTLZ 03088444	VNDHTLZ 03088531		
470	3/13/2008	Vanda Pharmaceuticals Inc. Form 10-K	VNDHTLZ 03088532	VNDHTLZ 03088615		
471	3/13/2009	Vanda Pharmaceuticals Inc. Form 10-K	VNDHTLZ 03088616	VNDHTLZ 03088704		
472	3/15/2010	Vanda Pharmaceuticals Inc. Form 10-K	VNDHTLZ 03088705	VNDHTLZ 03088929		
473	3/10/2011	Vanda Pharmaceuticals Inc. Form 10-K	VNDHTLZ 03088930	VNDHTLZ 03088941		
474	3/9/2012	Vanda Pharmaceuticals Inc. Form 10-K	VNDHTLZ 03089042	VNDHTLZ 03089157		

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475	2/26/2013	Vanda Pharmaceuticals Inc. Form 10-K	VNDHTLZ 03089158	VNDHTLZ 03089254		
476	2/25/2014	Vanda Pharmaceuticals Inc. Form 10-K	VNDHTLZ 03089255	VNDHTLZ 03089357		
477	2/26/2020	Vanda Pharmaceuticals Inc. Form 10-K	VNDHTLZ 03089358	VNDHTLZ 03089527		
478		IQVIA Channel Dynamics	VNDHTLZ 03089528	VNDHTLZ 03089528		
479		Consumer Price Index for All Urban Consumers: All Items in U.S. City Average, Monthly, Not Seasonally Adjusted, U.S. Bureau of Labor Statistics	VNDHTLZ 03089529	VNDHTLZ 03089529		
480	3/10/2020	Decision Resources Group	VNDHTLZ 03089530	VNDHTLZ 03089571		
481		Search Orphan Drug Designations and Approvals, FDA	VNDHTLZ 03089572	VNDHTLZ 03089572		
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483	1994	Tucker, Clinical Implications Of Genetic Polymorphism In Drug Metabolism, 46 J. Pharm. Pharmacology 417	VNDHTLZ 03089844	VNDHTLZ 03089851		
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485	10/1/1997	Middleton, B., et al., <i>Complex Effects of Melatonin on Human Circadian Rhythms in Constant Dim Light</i> , Journal of Biological Rhythms Volume 12, No. 5, 1997	VNDHTLZ 03089884	VNDHTLZ 03089896		
486	12/1/1997	Czeisler, C., <i>Commentary: Evidence for Melatonin as a Circadian Phase-Shifting Agent</i> , JOURNAL OF BIOLOGICAL RHYTHMS, Vol. 12 No. 6, 1997	VNDHTLZ 03089897	VNDHTLZ 03089902		

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487	1991	Aldhous, M.E., <i>Assessment of melatonin rhythms and the sleep-wake cycle in blind subjects</i> , John Libbey & Co Ltd 1991	VNDHTLZ 03089903	VNDHTLZ 03089905		
488	1992	Lewy et al., <i>Melatonin Shifts Human Circadian Rhythms According To A Phaseresponse Curve</i> , 9 Chronobiology International 380	VNDHTLZ 03089927	VNDHTLZ 03089939		
489	4/23/2013	Terron et al. Melatonin Reduces Bodyweight Gain And Increases Nocturnal Activity In Male Wistar Rats, 118 Physiology And Behavior 12 (2012)	VNDHTLZ 03089945	VNDHTLZ 03089950		
490	4/2/1988	Arendt, J., <i>Synchronisation of a Disturbed Sleep-Wake Cycle in a Blind Man by Melatonin Treatment</i> , The Lancet, 1999	VNDHTLZ 03089981	VNDHTLZ 03089982		
491	1978	Kokkoris et al. Long-Term Ambulatory Temperature Monitoring In A Subject With Hypernchthermal Sleep Wake Cycle Disturbance, Sleep (1978)	VNDHTLZ 03089983	VNDHTLZ 03089996		
492	1980	Czeisler et al. Human Sleep: Its Duration And Organization Depend On Circadian Phase, 210 Science 1264-67 (1980)	VNDHTLZ 03089997	VNDHTLZ 03090001		
493	1993	Klein et al. Circadian Sleep Regulation In The Absence Of Light Perception: Chronic Non-24-Hour Circadian Rhythm Disorder In A Blind Man With A Regular 24-Hour Sleep Wake Cycle, 16 Sleep 333 (1993)	VNDHTLZ 03090002	VNDHTLZ 03090013		
494	2011	Kathryn Reid & Phyllis Zee, The Handbook Of Clinical Neurology: Sleep Disorders, 966-67 (2012)	VNDHTLZ 03090034	VNDHTLZ 03090048		
495	2013	Czeisler, Casting Light On Sleep Deficiency, 497 Nature (2013).	VNDHTLZ 03090049	VNDHTLZ 03090049		
496	1981	Czeisler et al. Chronotherapy: Resetting The Circadian Clocks Of Patients With Delayed Sleep Phase Insomnia, Sleep 1981; 4:1-21.	VNDHTLZ 03090050	VNDHTLZ 03090070		

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497	1995	Dijk et al. Light Treatment For Sleep Disorders: Consensus Report. Basic Properties Of Circadian Physiology And Sleep Regulation, 10 J Biol. Rhythms 113-25 (1995)	VNDHTLZ 03090071	VNDHTLZ 03090083		
498	1994	Dijk And Czeisler, Paradoxical Timing Of The Circadian Rhythm Of Sleep Propensity Serves To Consolidate Sleep And Wakefulness In Humans, 166 Neurosci Letters 63-8 (1994)	VNDHTLZ 03090084	VNDHTLZ 03090089		
499	1987	Sack et al., <i>Free-Running Melatonin Rhythms In Blind People: Phase Shifts With Melatonin And Triazolam Administration</i> , In Temporal Disorder In Human Oscillatory Systems (1987)	VNDHTLZ 03090090	VNDHTLZ 03090095		
500	2018	Hull et al. Suppression Of Melatonin Secretion In Totally Visually Blind People By Ocular Exposure To White Light: Clinical Characteristics, 125 Ophthalmology (2018)	VNDHTLZ 03090096	VNDHTLZ 03090107		
501	2013	Paolo Girardi et al. Sleep Medicine: Clinical Practice (2013)	VNDHTLZ 03090108	VNDHTLZ 03090119		
502	2014	Mcgonigle, Animal Models Of Human Disease: Challenges In Enabling Translation, Biochemical Pharmacology (2014)	VNDHTLZ 03091791	VNDHTLZ 03091800		
503	1995	McKinnon et al. <i>Characterization of CYP3A Gene Subfamily Expression in Human Gastrointestinal Tissues</i>	VNDHTLZ 03091809	VNDHTLZ 03091817		
504	2010	Nestler, Animal Models Of Neuropsychiatric Disorders, Nature Neuroscience (2010)	VNDHTLZ 03091818	VNDHTLZ 03091835		
505	3/28/2008	Jazz Pharmaceuticals, Form 10-K 2007	VNDHTLZ 03091836	VNDHTLZ 03092167		
506	3/2010	Harvard Medical School <i>Treating Social Anxiety Disorder</i> , Harvard Health Publishing	VNDHTLZ 03092168	VNDHTLZ 030921717		
507	8/3/2020	Brigham Clinical Research News, Investigating Treatments For Non-24 Disorder, Brigham Clinical & Research News	VNDHTLZ 03092172	VNDHTLZ 03092173		
508	3/2019	Cimzia (Certolizumab) Injection, Label	VNDHTLZ 03092174	VNDHTLZ 03092217		

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509		Advil Tablets, 200 Mg, Label	VNDHTLZ 03092218	VNDHTLZ 03092220		
510	2/1976	Czeisler, et al. Episodic 24-Hour Cortisol Secretory Patterns In Patients Awaiting Elective Cardiac Surgery, 42(2) Journal Of Clinical Endocrinology & Metabolism 273	VNDHTLZ 03095145	VNDHTLZ 03095155		
511	1983	Weitzman, et al. Cortisol Secretion Is Inhibited During Sleep In Normal Man, 56(2) Journal Of Clinical Endocrinology & Metabolism 352 (1983)	VNDHTLZ 03095156	VNDHTLZ 03095162		
512	7/2007	Zeitzer, et al. Plasma Melatonin Rhythms In Young And Older Humans During Sleep, Sleep Deprivation, And Wake, 30(11) Sleep 1437 (2007)	VNDHTLZ 03095163	VNDHTLZ 03095169		
513	3/2013	Scheer, et al. The Internal Circadian Clock Increases Hunger And Appetite In The Evening Independent Of Food Intake And Other Behaviors, 21(3) Obesity (Silver Spring) 421 (2013)	VNDHTLZ 03095170	VNDHTLZ 03095177		
514	2/2/2018	Rahman et al., Functional Decoupling Of Melatonin Suppression And Circadian Phase Resetting In Humans, 596.11 J Pysiol 2147 (2018)	VNDHTLZ 03095178	VNDHTLZ 03095188		
515	2019	Rahman, et al. Characterizing The Temporal Dynamics Of Melatonin And Cortisol Changes In Response To Nocturnal Light Exposure, 9 Scientific Reports 19720 (2019)	VNDHTLZ 03095189	VNDHTLZ 03095200		
516	10/22/2013	Nda No. 205,677, Administrative And Correspondence Documents	VNDHTLZ 03095201	VNDHTLZ 03095349		
517	12/1998	FDA, Provigil Label	VNDHTLZ 03095350	VNDHTLZ 03095377		
518	8/1999	FDA, Sonata Label	VNDHTLZ 03095378	VNDHTLZ 03095403		
519	8/13/1999	FDA, Sonata Approval Letter	VNDHTLZ 03095404	VNDHTLZ 03095407		
520	1/2004	FDA, Provigil Label	VNDHTLZ 03095408	VNDHTLZ 03095442		

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521	7/22/2005	FDA, Rozerem Approval Letter	VNDHTLZ 03095443	VNDHTLZ 03095446		
522	6/2007	FDA, Nuvigil Label	VNDHTLZ 03095447	VNDHTLZ 03095486		
523	5/2014	FDA, Lunesta Label	VNDHTLZ 03095487	VNDHTLZ 03095512		
524	1/2015	FDA, Provigil Label	VNDHTLZ 03095513	VNDHTLZ 03095532		
525	5/16/2016	Evaluating the Effects of Tasimelteon vs Placebo on Sleep Disturbances in SMS, Vanda Pharmaceuticals Inc., Identification No. NCT02231008	VNDHTLZ 03095533	VNDHTLZ 03095538		
526	6/26/2018	A Proof of Concept Study to Evaluate the Effects of Tasimelteon and Placebo in Travelers with Jet Lag Disorder, Vanda Pharmaceuticals Inc., Identification No. NCT03291041	VNDHTLZ 03095539	VNDHTLZ 03095543		
527	12/2016	FDA, Ambien Label	VNDHTLZ 03095544	VNDHTLZ 03095567		
528	2/2017	FDA, Nuvigil Label	VNDHTLZ 03095568	VNDHTLZ 03095592		
529	12/2018	FDA, Rozerem Label	VNDHTLZ 03095593	VNDHTLZ 03095610		
530	4/22/20	2020 Annual Report of the Board of Trustees of the Federal Old-age and Survivors Insurance and Federal Disability Insurance Trust Funds, Social Security Administration	VNDHTLZ 03095611	VNDHTLZ 03095886		
531	12/1/2020	FDA, Hetlioz Supplemental Approval Letter	VNDHTLZ 03095887	VNDHTLZ 03095890		
532	12/1/2020	FDA Approves HETLIOZ® (tasimelteon) for the Treatment of Nighttime Sleep Disturbances in Smith-Magenis Syndrome, Vanda Pharmaceuticals Inc.	VNDHTLZ 03095891	VNDHTLZ 03095892		
533	7/14/1995	FDA, Ambien Approval Letter	VNDHTLZ 03095893	VNDHTLZ 03095912		

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534	1/17/2021	What Do I Need to Know about Specialty Drugs? Blue Cross Blue Shield Blue Care Network of Michigan	VNDHTLZ 03095913	VNDHTLZ 03095914		
535	1/17/2021	Clinical Pharmacy and Specialty Drugs Prior Authorization Programs, United Healthcare	VNDHTLZ 03095915	VNDHTLZ 03095917		
536	1/25/2021	Our Story, CoverMyMeds	VNDHTLZ 03095918	VNDHTLZ 03095921		
537		Consumer Price Index for All Urban Consumers: All Items in U.S. City Average, Monthly, Not Seasonally Adjusted, U.S. Bureau of Labor Statistics	VNDHTLZ 03095922	VNDHTLZ 03095922		
538	2020	Employer Health Benefits 2020 Annual Survey, Kaiser Family Foundation,	VNDHTLZ 03095923	VNDHTLZ 03096136		
539	2005	Grabowski, H., <i>Increasing R&D Incentives for Neglected Diseases: Lessons from the Orphan Drug Act</i> , International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime, 2005, K. Maskus and J. Reichman (Eds.), Cambridge, UK: Cambridge University Press, pp. 457–480	VNDHTLZ 03096137	VNDHTLZ 03096163		
540	9/2012	Harrington, S. E., <i>Cost of Capital for Pharmaceutical, Biotechnology, and Medical Device Firms</i> , The Oxford Handbook of the Economics of the Biopharmaceutical Industry, 2012, P. M. Danzon and S. Nicholson (Eds.), New York, NY: Oxford University Press, pp. 75–99	VNDHTLZ 03096164	VNDHTLZ 03096205		
541	2020	Prescribing HELTIOZ® (tasimelteon): An Instructional Guide, Vanda Pharmaceuticals Inc.	VNDHTLZ 03096206	VNDHTLZ 03096208		
542	12/15/2004	FDA, Lunesta Approval Letter	VNDHTLZ 03096209	VNDHTLZ 03096228		
543		Medicare Provider Utilization and Payment Data: Part D Prescriber	VNDHTLZ 03096229	VNDHTLZ 03096229		

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544	7/25/2003	MGI Pharma and Helsinn Healthcare SA Announce FDA Approval of Aloxi™, MGI Pharma and Helsinn Healthcare Press Release	VNDHTLZ 03096230	VNDHTLZ 03096233		
545	6/15/2007	FDA, Nuvigil Approval Letter	VNDHTLZ 03096234	VNDHTLZ 03096240		
546	2/2/2019	Nuvigil vs. Provigil: How Are They Similar and Different? Healthline	VNDHTLZ 03096241	VNDHTLZ 03096255		
547	7/3/2014	O'Connell, K. and A. Pariser, (2014) Clinical Trial Safety Population Size: Analysis of Drug Approvals for Rare and Common Indications by FDA Center for Drug Evaluation and Research, Expert Opinion on Orphan Drugs, 2(9), pp. 869–875	VNDHTLZ 03096256	VNDHTLZ 03096263		
548	1/7/2021	Orphan Products: Hope for People with Rare Diseases, FDA	VNDHTLZ 03096264	VNDHTLZ 03096267		
549		Prior Authorization, Avella Specialty Pharmacy	VNDHTLZ 03096277	VNDHTLZ 03096278		
550	12/24/1998	FDA, Provigil Approval Letter	VNDHTLZ 03096281	VNDHTLZ 03096286		
551		Rare Diseases at FDA, FDA	VNDHTLZ 03096287	VNDHTLZ 03096291		
552	2/24/2020	Ahmed, S. <i>Rethinking the Prior Authorization Process</i> , Pharmacy Times	VNDHTLZ 03096292	VNDHTLZ 03096301		
553	2010	Trusheim, M., et al., (2010) Characterizing Markets for Biopharmaceutical Innovations: Do Biologics Differ from Small Molecules? Forum for Health Economics & Policy, 13(1), pp. 1–43	VNDHTLZ 03096302	VNDHTLZ 03096347		
554	5/22/2020	Updated Contract Year (CY) 2021 Final Part D Bidding Instructions, HHS	VNDHTLZ 03096348	VNDHTLZ 03096349		
555	3/3/2020	Wouters, O., et al., (2020) <i>Estimated Research and Development Investment to Bring a New Medicine to Market</i> , 2009-2018, Journal of the American Medical Association, 323(9), pp. 844–853	VNDHTLZ 03096353	VNDHTLZ 03096362		

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556	10/1/2020	UnitedHealthcare, Complete Drug List (Formulary) 2021: AARP Medicare Advantage Choice (PPO), AARP Medicare Advantage Choice (Regional PPO)	VNDHTLZ 03096363	VNDHTLZ 03096495		
557	10/1/2020	UnitedHealthcare, Complete Drug List (Formulary) 2021: AARP MedicareRx Preferred (PDP)	VNDHTLZ 03096496	VNDHTLZ 03096627		
558	10/1/2020	UnitedHealthcare, Complete Drug List (Formulary) 2021, AARP MedicareRx Saver Plus (PDP),	VNDHTLZ 03096628	VNDHTLZ 03096744		
559	10/1/2020	UnitedHealthcare, Complete Drug List (Formulary) 2021, AARP MedicareRx Walgreens (PDP)	VNDHTLZ 03096745	VNDHTLZ 03096862		
560	10/1/2020	UnitedHealthcare, Complete Drug List (Formulary) 3032: AARP Medicare Advantage (HMO), AARP Medicare Advantage (HMO-POS), AARP Medicare Advantage Focus (HMO-POS)	VNDHTLZ 03096863	VNDHTLZ 03096995		
561	2021	Aetna, Drug Search: 2021 Advanced Control Plan – Aetna, Formulary Navigator	VNDHTLZ 03096996	VNDHTLZ 03096997		
562	1/1/2021	Aetna, 2021 Comprehensive Formulary: Aetna Medicare (List of Covered Drugs) B2,	VNDHTLZ 03096998	VNDHTLZ 03097113		
563	2019	Aetna, Special Drug Coverage Reviews: Specialty Drugs Requiring Prior Authorization, 2019 Aetna Standard Plan,	VNDHTLZ 03097114	VNDHTLZ 03097119		
564	1/2021	Anthem BlueCross California National, Drug Search: National Drug List 3-Tier, Formulary Navigator	VNDHTLZ 03097120	VNDHTLZ 03097122		
565		Find Medicines, Prime Therapeutics	VNDHTLZ 03097123	VNDHTLZ 03097123		
566	1/2021	Anthem BlueCross BlueShield of Texas, Balanced Drug List,	VNDHTLZ 03097124	VNDHTLZ 03097309		

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567	1/1/2021	2021 Cigna Drug Lists	VNDHTLZ 03097310	VNDHTLZ 03097310		
568		Carefirst, Specialty Guideline Management: Hetlioz (Tasimelteon), CVS Caremark	VNDHTLZ 03097313	VNDHTLZ 03097313		
569	8/14/2020	Elixir Insurance, Elixir RxPlus (PDP): 2021 Formulary (List of Covered Drugs)	VNDHTLZ 03097314	VNDHTLZ 03097422		
570		Express Scripts Medicare (PDP) – Value, Search Results for Hetlioz CAP 20MG, Express Scripts	VNDHTLZ 03097423	VNDHTLZ 03097423		
571	2021	SERS, Express Scripts Prescription Drug Coverage Guide	VNDHTLZ 03097424	VNDHTLZ 03097437		
572	1/1/2021	FEP, FEP 5 Tier Managed Rx Drug Formulary (807) Basic Option	VNDHTLZ 03097438	VNDHTLZ 03097532		
573	1/1/2021	FEP, FEP 5 Tier Rx Drug Formulary (607) Standard Option	VNDHTLZ 03097533	VNDHTLZ 03097628		
574	2021	Fingertip Formulary	VNDHTLZ 03097629	VNDHTLZ 03097629		
575	12/14/2020	Humana, Prescription Drug Guide, Humana Formulary, List of Covered Drugs: Humana Basic Rx Plan (PDP)	VNDHTLZ 03097633	VNDHTLZ 03097744		
576	12/14/2020	Humana, Prescription Drug Guide, Humana Formulary, List of Covered Drugs: HumanaChoice (PPO), Humana Care Extra (PPO), Humana Together (PPO SNP), HumanaChoice Florida (PPO), 2021	VNDHTLZ 03097745	VNDHTLZ 03097880		
577	12/14/2020	Humana, Prescription Drug Guide, Humana Formulary, List of Covered Drugs: Humana Community (HMO), Humana Gold Plus (HMO), Humana Cleveland Clinic Preferred (HMO), Humana LCMC Advantage (HMO), Humana-Ochsner Network (HMO), 2021	VNDHTLZ 03097881	VNDHTLZ 03098016		
578	12/14/2020	Humana, Prescription Drug Guide, Humana Formulary, List of Covered Drugs: Humana Gold Plus (HMO)," 2021	VNDHTLZ 03098017	VNDHTLZ 03098152		

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579	12/14/2020	Humana, Prescription Drug Guide, Humana Formulary, List of Covered Drugs: Humana Premier Rx Plan (PDP), 2021	VNDHTLZ 03098153	VNDHTLZ 03098272		
580	12/14/2020	Humana Walmart, Prescription Drug Guide, Humana Formulary, List of Covered Drugs: Humana Walmart Value Rx Plan (PDP)	VNDHTLZ 03098273	VNDHTLZ 03098388		
581	12/1/2020	Kaiser Permanente, Kaiser Permanente: 2020 Northern California Commercial HMO Formulary	VNDHTLZ 03098389	VNDHTLZ 03098552		
582	9/2020	Kaiser Permanente, 2021 Comprehensive Formulary: Kaiser Permanente Senior Advantage (HMO)	VNDHTLZ 03098553	VNDHTLZ 03098687		
583	12/1/2020	Kaiser Permanente, Kaiser Permanente: 2020 Southern California Commercial HMO Formulary	VNDHTLZ 03098688	VNDHTLZ 03098839		
584	1/2021	RxSense, RxSense Performance Formulary	VNDHTLZ 03098840	VNDHTLZ 03099067		
585	12/1/2020	Aetna, SilverScript Choice (PDP), 2021 Formulary (List of Covered Drugs)	VNDHTLZ 03099068	VNDHTLZ 03099145		
586		TRICARE Formulary Search, Express Scripts Tricare	VNDHTLZ 03099146	VNDHTLZ 03099146		
587	10/1/2020	UnitedHealthcare, Complete Drug List (Formulary) 2021: UnitedHealthcare Dual Complete LP (HMO D-SNP)	VNDHTLZ 03099147	VNDHTLZ 03099282		
588	2020	UnitedHealthcare, Clinical Pharmacy Programs, Program Number 2020 P 2033-10, Program: Prior Authorization/Medical Necessity, Medication: Hetlioz (tasimelteon), 2020	VNDHTLZ 03099283	VNDHTLZ 03099285		
589	3/2015	VA Pharmacy Benefits Management Services, Tasimelteon (Hetloiz); Criteria for Use	VNDHTLZ 03099286	VNDHTLZ 03099286		
590		Prescription Drug List, OptumRx	VNDHTLZ 03099287	VNDHTLZ 03099290		
591	1/2021	Search Results for Hetlioz Oral Capsule 20 mg, Wellcar	VNDHTLZ 03099291	VNDHTLZ 03099292		

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592	9/26/2001	Jd Gardner et al. Measurement Of Meal-Stimulated Gastric Acid Secretion By In Vitro Gastric Autotitration., 92 J Appl Physio. 427-434	VNDHTLZ 03099305	VNDHTLZ 03099312		
593	12/1/1987	La Houghton et al. Effect Of Food Consistency On Gastric Emptying In Man, 28 Gut 1584-1588	VNDHTLZ 03099313	VNDHTLZ 03099317		
594	1979	Hs Kroop et al. Effect Of Water And Fat On Gastric Emptying Of Solid Meals. 77 Gastroenterology 997-1000	VNDHTLZ 03099318	VNDHTLZ 03099321		
595	8/2019	FDA, Sonata Label	VNDHTLZ 03099353	VNDHTLZ 03099376		
596	3/25/2016	Observational Study to Investigate the Melatonin and Cortisol Circadian Rhythms of Individuals with Smith-Magenis Syndrome (SMS), Vanda Pharmaceuticals Inc., Identification No. NCT02180451	VNDHTLZ 03099378	VNDHTLZ 03099383		
597	3/4/2008	Basu, P., et al., (2008) Analysis of Manufacturing Costs in Pharmaceutical Companies, Journal of Pharmaceutical Innovation, 3, pp. 30-40	VNDHTLZ 03099384	VNDHTLZ 03099394		
598	5/7/2020	Vanda Pharmaceuticals Inc. Form 10-Q	VNDHTLZ 03099395	VNDHTLZ 03099450		
599	8/6/2020	Vanda Pharmaceuticals Inc. Form 10-Q	VNDHTLZ 03099451	VNDHTLZ 03099509		
600	10/29/2020	Vanda Pharmaceuticals Inc. Form 10-Q	VNDHTLZ 03099510	VNDHTLZ 03099568		
601	9/14/2015	Handwerk, <i>Americans are Eating Later, and that may Contribute to Weight Troubles</i> , Smithsonian Magazine	VNDHTLZ 03103114	VNDHTLZ 03103116		
602		Consumer Price Index for All Urban Consumers: All Items in U.S. City Average, Monthly, Not Seasonally Adjusted, U.S. Bureau of Labor Statistics	VNDHTLZ 03103117	VNDHTLZ 03103117		
603	2012	Massive Health, the Eatery, Nighttime Snacking in the U.S.	VNDHTLZ 03103126	VNDHTLZ 03103135		

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604	5/6/2021	Vanda Pharmaceuticals Inc., Form 10-Q	VNDHTLZ 03103136	VNDHTLZ 03103171		
605	7/1955	Stunkard et al. The Night-Eating Syndrome—A Pattern Of Food Intake Among Certain Obese Patients, 19 Am J Med. 78-87 (1955)	VNDHTLZ 03103210	VNDHTLZ 03103218		
606	8/24/2015	Van Allen, Why Eating Late At Night May Be Particularly Bad For You And Your Diet, Washington Post	VNDHTLZ 03103219	VNDHTLZ 03103223		
607	2/11/2021	Vanda Pharmaceuticals Inc., Form 10-K	VNDHTLZ 03103224	VNDHTLZ 031033440		
608	2011	National Sleep Foundation, 2011 Sleep In America Poll (2011)	VNDHTLZ 03103356	VNDHTLZ 03103431		
609	3/27/2001	National Sleep Foundation, 2001 Sleep In America Poll (2001)	VNDHTLZ 03103432	VNDHTLZ 03103452		
610	4/18/2018	"Notice of Denial of Medicare Prescription Drug Coverage," Cigna HealthSpring	VNDHTLZ 00344934	VNDHTLZ 00344941		
611	4/25/2016	"Notice of Denial of Medicare Prescription Drug Coverage," Florida Blue	VNDHTLZ 00951877	VNDHTLZ 00951888		
612	6/10/2012	"A National Registry of Totally Blind Individuals with Sleep-Wake Complaints"	VNDHTLZ 02021372	VNDHTLZ 02021372		
613	5/6/1999	"BMS-214778 Investigator Brochure," BMS, Part A	VNDHTLZ 02057587	VNDHTLZ 02057636		
614	5/6/1999	"BMS-214778 Investigator Brochure," BMS, Part B	VNDHTLZ 02057637	VNDHTLZ 02057676		
615		BMS-214778 CN116-002 Final Study Report	VNDHTLZ 02468838	VNDHTLZ 02468995		
616		"BMS-214778 CN116-003 Abbreviated Final Study Report," BMS	VNDHTLZ 02470842	VNDHTLZ 02470845		
617		Consumer Marketing Overview	VNDHTLZ 02480958	VNDHTLZ 02481014		
618	11/26/2013	"Transitioning Coverage, Maintaining Overweight Rating," PiperJaffray	VNDHTLZ 02491438	VNDHTLZ 02491466		
619	7/28/2016	Vanda Pharmaceuticals Inc. Form 10-Q	VNDHTLZ 02494766	VNDHTLZ 02494806		
620		What Is A Specialty Drug? Pharmaceutical Care Management Association	VNDHTLZ 03096350	VNDHTLZ 03096352		
621	2/3/2014	Herman, A.O. "Sleep Disorder in the Blind," NEJM Journal Watch	VNDHTLZ 03103125	VNDHTLZ 03103125		
622	7/29/2021	Vanda Pharmaceuticals Inc. Form 10-Q	VNDHTLZ 03103172	VNDHTLZ 03103209		
623	10/2019	Hetlioz Label (October 2019)				

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624	9/3/2021	Defendants' Disclosure of Obviousness Combinations				
625		Robert Perni, LinkedIn Profile				
626	10/30/2019	Apotex Inc. and Apotex Corp.'s Objections and Responses to Vanda's Notice of Deposition of Apotex Inc. and Apotex Corp.				
627	2/27/2019	Certificate of Analysis VEC-162				
628	10/21/2020	Notice of Deposition of Apotex Inc. and Apotex Corp.				
629	7/16/2021	Apotex Inc. and Apotex Corp.'s Objections and Responses to Vanda's Notice of Deposition of Apotex Inc. and Apotex Corp.				
630	10/31/2019	Defendants MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited's Objections and Responses to Plaintiff's Notice of Deposition Pursuant to Fed. R. Civ. P. 30(b)(6)				
631	3/30/2018	Letter from B. Cooper to Vanda Pharmaceuticals, Inc. re: Notice of ANDA No. 211654 - Tasimelteon Capsules, 20 mg				
632	5/13/2019	Letter from B. Cooper to Vanda Pharmaceuticals, Inc. re: Notice of ANDA No. 211654 - Tasimelteon Capsules, 20 mg				
633	11/8/2019	Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations - Patent and Exclusivity for: N205677 - TASIMELTEON (HETLIOZ) CAPSULE 20MG				
634	6/20/2019	MSN's Responses to Vanda's First Set of Joint Interrogatories to Defendants (Nos. 1-8)				
635	11/12/2020	MSN's Responses and Objections to Vanda's Notice of Deposition Pursuant to Fed. R. Civ. P. 30(b)(6)				

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636	1/8/2020	Letter from K. Warner to Vanda Pharmaceuticals, Inc. re: Notice of ANDA No. 211654 Tasimelteon Capsules, 20 mg				
637	2/10/2020	Letter from K. Warner to Vanda Pharmaceuticals, Inc. re: Notice of ANDA No. 211654 Tasimelteon Capsules, 20 mg				
638	7/29/2019	MSN's First Amended Responses and Objections to Vanda's Notice of Deposition Pursuant to Fed. R. Civ. P. 30(b)(6)				
639	3/23/2021	Letter from B. Cooper to Vanda Pharmaceuticals, Inc. re: Notice of ANDA No. 211654 Tasimelteon Capsules, 20 mg				
640		FDA, Guidance, Compliance & Regulatory Information (Biologics)				
641	2021	Associate, Cambridge English Dictionary (2021)				
642	2021	Associated, Merriam Webster (2021)				
643	5/1/2010	Armstrong, Pharma's Orphans, Website				
644	3/16/2020	21 CFR § 316.20				
645	2017	Mchill, et al. Later Circadian Timing Of Food Intake Is Associated With Increased Body Fat, 106 Am J Clin Nutr 1213 (2017)				
646	9/14/2021	Nightfood, Inc., Nighttime Snacking In The U.S. (2020)				
647	2006	Winkelman, <i>Sleep-Related Eating Disorder and Night Eating Syndrom: Sleep Disorders, Eating Disorders, or Both?</i> SLEEP 2006;29(7):949-95				
648	3/1/2019	Gobbi and Comai, <i>Differential Function of Melatonin MT1 and MT2 Receptors in REM and NREM Sleep</i> , Front. Endocrinol.				

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649	11/2016	Flulaval Influenza Vaccine, Label				
650	8/2019	Ambien tablets, Label				
651	8/2019	Lunesta tablets, Label				
652	9/2020	Boostrix injectable suspension, Label				
653	2014	American Academy of Sleep Medicine, <i>Insomnia</i> , International Classification of Sleep Disorders, 3rd Edition, 2014				
654	2014	American Academy of Sleep Medicine, <i>Non-24-Hour Sleep-Wake Rhythm Disorder</i> , International Classification of Sleep Disorders, 3rd Edition, 2014				
655	2014	American Academy of Sleep Medicine, <i>Restless Legs Syndrome</i> , International Classification of Sleep Disorders, 3rd Edition, 2014				
656	6/2021	Aduhelm Label				
657		FDA, Table of Surrogate Endpoints That Were the Basis of Drug Approval or Licensure				
658	4/2003	Ekins et al. In Vitro And Pharmacophore Insights Into Cyp3A Enzymes, 24 Trends In Pharmacological Sciences 161				
659	2015	Kazmi et al. <i>A Long-Standing Mystery Solved: The Formation Of 3-Hydroxydesloratadine Is Catalyzed By Cyp2C8 But Prior Glucuronidation Of Desloratadine By Udp-Glucuronosyltransferase 2B10 Is An Obligatory Requirement</i> , 43 Drug Metabolism & Disposition 523				
660	1984	Turnbull et al. Therapeutic Serum Concentration Of Phenytoin: The Influence Of Seizure Type, 47 Journal Of Neurology, Neurosurgery, And Psychiatry 231				

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661	6/2010	Hv Chavda et al. Biopharmaceutics Classification System, 1 Sys. Rev. Pharm.				
662	1989	Mg Velchik, et al. The Effect Of Meal Energy Content On Gastric Emptying, 30 J. Nucl. Med. 1106-10				
663	7/3/2019	Vanda's Objections and Responses to Defendants' First Set of Joint Interrogatories to Vanda (Nos. 1-10)				
664	11/27/2019	Vanda's Objections and Responses to Defendants' Second Set of Joint Interrogatories to Plaintiff (Nos. 11-15)				
665	11/27/2019	Vanda's Responses and Objections to MSN's First Set of Interrogatories to Plaintiff (Nos. 1-4)				
666	11/27/2019	Vanda's Responses and Objections to Teva's First Set of Interrogatories to Plaintiff (Nos. 1-8)				
667	12/17/2019	Vanda's Supplemental Objections and Responses to Defendants' First Set of Joint Interrogatories to Vanda (NOS. 1-4, 6-8, and 10)				
668	12/20/2019	Vanda's Second Supplemental Objections and Responses to Defendants' First Set of Joint Interrogatories to Vanda (No. 3)				
669	12/24/2019	Vanda's Amended Objections and Responses to Teva's First Set of Interrogatories to Plaintiff (Nos. 2 and 5-7)				
670	1/15/2020	Vanda's Supplemental Objections and Responses to Teva's First Set of Interrogatories to Plaintiff (No. 8)				
671	10/26/2020	Vanda's Objections and Responses to Defendants' First Set of Interrogatories (Nos. 1-4) Regarding U.S. Patent Nos. 10,376,487 and 10,449,176				
672	11/16/2020	Vanda's First Supplemental Objections and Responses to Defendants' First Set of Interrogatories to Vanda (Nos. 2 & 4) Regarding U.S. Patent Nos. 10,376,487 and 10,449,176				

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673	11/20/2020	Vanda's Objections and Responses to Defendants' Second of Interrogatories to Vanda (No. 5) Regarding U.S. Patent Nos. 10,376,487 and 10,449,176				
674	6/11/2021	Vanda's Objections and Responses to Defendants' First Set of Interrogatories to Vanda (Nos. 1-5) Regarding U.S. Patent Nos. 10,610,510; 10,610,511; 10,829,465; and 10,611,744				
675		Emens and Lewy, <i>Sleep and Circadian Rhythms in</i>				
676	7/19/2010	Clinical Trials, Efficacy of Ramelteon on Speeding up Sleep in Subjects with Delayed Sleep Phase Syndrome				
677	2000	Zeitzer et al. Sensitivity of the Human Circadian Pacemaker to Nocturnal Light: Melatonin Phase Resetting and Suppression				
678	2005	Circadian Rhythm Sleep Disorder, Free-running Type (nonentrained type), ICSD II I-VIII				
679	12/6/2002	Klerman et al. <i>Photic Resetting of the Human Circadian Pacemaker in the Absence of Conscious Vision</i> , JOURNAL OF BIOLOGICAL RHYTHMS, Vol. 17 No. 6, December 2002				
680	1999	<i>Hour Period of the Human Circadian Pacemaker</i> ,				
681	3/1994	Dollins et al. Effect Of Inducing Nocturnal Serum Melatonin Concentrations In Daytime On Sleep, Mood, Body Temperature, And Performance, 91 Proceedings Of The National Academy Of Sciences Of The U.S.A 1824 (1990)				
682	2/3/2014	Herman, Fda Approves First Drug To Treat Circadian Rhythm Sleep Disorder In The Blind, Nejm Journal Watch				
683	2/2014	Greenblatt, <i>In Vitro Prediction of Clinical Drug Interactions With CYP3A Substrates: We Are Not There Yet</i>				

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684	1/2006	Obach et al., <i>The Utility of in Vitro Cytochrome P450 Inhibition Data in the Prediction of Drug-Drug Interactions</i>				
685	2010	Von Moltke and Greenblatt, <i>Clinical Drug Interactions Due to Metabolic Inhibition: Prediction, Assessment, and Interpretation</i>				
686	12/1994	Von Moltke et al., <i>In Vitro Prediction of the Terfenadine-Ketoconazole Pharmacokinetic Interaction</i>				
687	1/1984	Hamann et al., <i>Clinical Pharmacokinetics of Verapamil</i>				
688	12/2020	Hetlioz Label (December 2020)				
689	2021	2021 Annual Report of the Board of Trustees of the Federal Old-age and Survivors Insurance and Federal Disability Insurance Trust Funds, Social Security Administration				
690	9/14/2017	Health Policy Brief: Formularies, Health Affairs				
691	10/2014	Orphan Drug Report 2014, EvaluatePharma				
692		Developing Products for Rare Diseases & Conditions				
693	2015	Berndt, E., et al., (2015) Decline in Economic Returns from New Drugs Raises Questions About Sustaining Innovations Health Affairs, 34(2), pp. 245–252				
694	2019	Quality of Life, Helsinn Group Sustainability Report – 2018, Helsinn, 2019				
695		Rare Disease Database, National Organization for Rare Disorders				
696		Search for Patents, United States Patent and Trademark Office				

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697	2010	DiMasi, J. A., et al. (2010) Trends in Risks Associated with New Drug Development: Success Rates for Investigational Drugs, Clinical Pharmacology & Therapeutics, 87(3), pp. 272-277				
698	2004	Hay, M., et al. (2014), Clinical Development Success Rates for Investigational Drugs, Nature Biotechnology, 32(1)				
699		Drugs@FDA: FDA-Approved Drugs, FDA				
700	7/22/2021	Chemours Co. FC v. Daikin Indus., 4 F.4th 1370 (Fed. Cir. 2021)				
701	10/29/2019	Teva's Objections and Responses to Vanda's Notice of Deposition of Teva Pharmaceuticals, USA, Inc.				
702		CV of Atul Kaushik				
703	10/2018	MHRA Public Assessment Report Decentralised Procedure - Teva UK Limited - PAR Melatonin Teva XL 2 mg PR tablets Celton XL 2 mg PR tablets				
704	11/1/2019	Email from D. Wells to D. Klein, et al. re: Teva's Deposition Responses				
705	3/22/2018	Letter from F. Majiduddin to Vanda Pharmaceuticals Inc. re: Notice of ANDA No. 211601 Tasinielteon, Capsules 20 mg, With Paragraph IV Certifications				
706	10/24/2018	Letter from F. Majiduddin to Vanda Pharmaceuticals Inc. re: Notice of ANDA No. 211601 Tasimelteon, Capsules 20 mg, With Paragraph IV Certifications Concerning U.S. Patent No. 10,071,977				

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707	2/6/2019	Letter from F. Majiduddin to Vanda Pharmaceuticals Inc. re: Notice of ANDA No. 211601 Tasimelteon, Capsules 20 mg, With Paragraph IV Certifications Concerning U.S. Patent No. 10,149,829				
708		CV of Vatsal Shah				
709	11/27/2019	Teva's Responses to Vanda's Second Set of Joint Interrogatories to Defendants (Nos. 9-10)				
710	11/27/2019	Teva's Responses to Vanda's First Set of Joint Interrogatories to Teva (Nos.1 &2)				
711	11/11/2020	Teva's Objections and Responses to Vanda's Notice of Deposition of Teva Pharmaceuticals, USA, Inc.				
712		Notice of Videotaped Deposition of Bairy				
713	3/22/2018	Teva Pharmaceuticals USA, Inc. 's Detailed Statement Of The Factual And Legal Bases That U.S. Reissue Patent No. RE46,604 And U.S. Patent Nos. 9,060,995, 9,539,234, 9,549,913, 9,730,910 And 9,855,241 Are Invalid, Unenforceable or Not Infringed				
714	3/22/2018	Letter from F. Majiduddin to Hoffman Warnick, LLC re Notice of ANDA No. 211601 Tasimelteon, Capsules 20mg, With Paragraph IV Certifications Concerning US Reissue Patent No. RE46,6044 and US Patent Nos. 9,060,996, 9,539,234, 9,549,913, 9,730,910 and 9,855,241				
715	10/15/2019	Notice of Videotaped Deposition of DeCicco				
716		Australian Government Department of Health, BLOOMS THE CHEMIST MELATONIN MR melatonin 2 mg modified release tablet blister pack				

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717	4/3/2017	Australian Government Department of Health, TERRY WHITE CHEMISTS MELATONIN MR melatonin 2 mg modified release tablet blister pack				
718	4/3/2017	Australian Government Department of Health, CHEMMART MELATONIN MR melatonin 2 mg modified release tablet blister pack				
719	4/3/2017	Australian Government Department of Health, MELATONIN MR APOTEX melatonin 2 mg modified release tablet blister pack				
720	4/3/2017	Australian Government Department of Health, APO-MELATONIN MR melatonin 2 mg modified release tablet blister pack				
721		Notice of Videotaped Deposition of Ehlert				
722	11/25/2018	Letter from Apotex to Vanda re Tasimelteon 20 mg: Notification of Certification of Noninfringement, Invalidity and/or Unenforceability of U.S. Patent No. 10,071,977 pursuant to § 505(i)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act				
723	4/2/2018	Letter from Apotex to Vanda re Tasimelteon, 20 mg: Notification of Certification of Noninfringement, Invalidity and/or Unenforceability of U.S. Patent Nos. 9,060,995, 9,539,234, 9,549,913, 9,730,910, 9,855,241, and RE46,604 pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act				
724		Notice of Videotaped Deposition of Kaushik				
725	11/26/2019	Notice of the Videotaped Deposition of Vatsal Shah				
726	10/15/2019	Notice of Videotaped Deposition of Singh				
727	2016	McDuff et al. <i>Thinking Economically About Commercial Success</i> , Landslide Vol. 9 No. 4				

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728	7/29/2021	Teva's Objections and Responses to Vanda's Notice of Deposition of Teva Pharmaceuticals, USA, Inc.				
729	7/9/2014	PTO '995 Patent Assignment Sheet; Reel 033273: Frames 0671-0676				
730	10/16/2014	PTO '910 Patent Assignment Sheet; Reel 033965: Frames 0395-0398				
731	10/27/2014	PTO '913 Patent Assignment Sheet; Reel 034037: Frames 0080-0083				
732	6/17/2015	PTO '234 Patent Assignment Sheet; Reel 035851: Frames 0806-0809				
733	8/11/2016	PTO '977 Patent Assignment Sheet; Reel 039405: Frames 0498-0503				
734	1/6/2017	PTO '241 Patent Assignment Sheet; Reel 040870: Frames 0702-0704				
735	1/6/2017	PTO '829 Patent Assignment Sheet; Reel 040874: Frames 0167-0177				
736	9/8/2017	PTO RE604 Patent Assignment Sheet; Reel 043531: Frames 0328-0329; Reel 037676: Frames 0086-0092				
737	9/8/2017	PTO RE604 Patent Assignment Sheet; Reel 043541: Frames 0342-0343; Reel 030932: Frames 0083-0087				
738	9/13/2019	PTO '511 Patent Assignment Sheet; Reel 050371: Frames 0058-0061				
739	7/28/2020	PTO '465 Patent Assignment Sheet; Reel 053328: Frames 0711-0723				
740	7/29/2020	PTO '977 Patent Assignment Sheet: Reel 053339: Frames 0291-0299				
741	10/15/2019	30(b)(6) Notice of Deposition of Apotex Inc. and Apotex Corp.				
742	10/21/2020	30(b)(6) Notice of Deposition of Apotex Inc. and Apotex Corp.				
743	10/21/2020	30(b)(6) Notice of Deposition of Apotex Inc. and Apotex Corp., Wave 2				
744	6/30/2021	30(b)(6) Notice of Deposition of Apotex Inc. and Apotex Corp.				

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745	10/15/2019	30(b)(6) Notice of Deposition of MSN Pharmaceuticals and MSN Laboratories Private Limited				
746	10/21/2020	30(b)(6) Notice of Deposition of MSN Pharmaceuticals and MSN Laboratories Private Limited, Wave 2				
747	6/30/2021	30(b)(6) Notice of Deposition of MSN Pharmaceuticals and MSN Laboratories Private Limited				
748	10/15/2019	30(b)(6) Notice of Deposition of Teva Pharmaceuticals USA, Inc.				
749	10/21/2020	30(b)(6) Notice of Deposition of Teva Pharmaceuticals USA, Inc.				
750	6/30/2021	30(b)(6) Notice of Deposition of Teva Pharmaceuticals USA, Inc.				
751	10/15/2019	Notice of Videotaped Deposition of Shah				
752	11/16/2019	Notice of Videotaped Deposition of Shah				
753	3/30/2018	Letter from B. Cooper to Vanda Pharmaceuticals, Inc. re: Notice of ANDA No. 211654 - Tasimelteon Capsules, 20 mg, PIV Letter				
754	5/13/2019	Letter from B. Cooper to Vanda Pharmaceuticals, Inc. re: Notice of ANDA No. 211654 - Tasimelteon Capsules, 20 mg, PIV Letter				
755	1/8/2020	Letter from K. Warner to Vanda Pharmaceuticals, Inc. re: Notice of ANDA No. 211654 Tasimelteon Capsules, 20 mg, PIV Letter				
756	2/10/2020	Letter from K. Warner to Vanda Pharmaceuticals, Inc. re: Notice of ANDA No. 211654 Tasimelteon Capsules, 20 mg, PIV Letter				
757	3/23/2021	Letter from B. Cooper to Vanda Pharmaceuticals, Inc. re: Notice of ANDA No. 211654 Tasimelteon Capsules, 20 mg				

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758	3/22/2018	Letter from F. Majiduddin to Vanda Pharmaceuticals Inc. re: Notice of ANDA No. 211601 Tasinielton, Capsules 20 mg, With Paragraph IV Certifications				
759	10/24/2019	Letter from F. Majiduddin to Vanda Pharmaceuticals Inc. re: Notice of ANDA No. 211601 Tasimelton, Capsules 20 mg, With Paragraph IV Certifications Concerning U.S. Patent No. 10,071,977				
760	2/6/2019	Letter from F. Majiduddin to Vanda Pharmaceuticals Inc. re: Notice of ANDA No. 211601 Tasimelton, Capsules 20 mg, With Paragraph IV Certifications Concerning U.S. Patent No. 10,149,829				
761	1/31/2020	Expert Report of Stephen C. Bergmeier, PH.D Regarding Infringement by Apotex of U.S. Patent No. 10,071,977, With Exhibits and/or Attachments				
762	1/31/2020	Expert Report of Stephen C. Bergmeier, PH.D Regarding Infringement by MSN of U.S. Patent No. 10,071,977, With Exhibits and/or Attachments				
763	1/31/2020	Expert Report of Stephen C. Bergmeier, PH.D Regarding Infringement by Teva of U.S. Patent No. 10,071,977, With Exhibits and/or Attachments				
764	7/27/2020	Addendum to Expert Report of Stephen C. Bergmeier, PH.D. Regarding Infringement by Apotex of U.S. Patent No. 10,071,977				
765	7/27/2020	Addendum to Expert Report of Stephen C. Bergmeier, PH.D. Regarding Infringement by Teva of U.S. Patent No. 10,071,977				
766	7/27/2020	Addendum to Expert Report of Stephen C. Bergmeier, PH.D. Regarding Infringement by MSN of U.S. Patent No. 10,071,977				
767	12/21/2020	Supplemental Expert Report of Stephen C. Bergmeier, PH. D. Regarding Infringement by MSN of U.S. Patent No. 10,071,977, With Exhibits and/or Attachments				

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768	12/21/2020	Supplemental Expert Report of Stephen C. Bergmeier, PH. D. Regarding Infringement by Teva of U.S. Patent No. 10,071,977, With Exhibits and/or Attachments				
769	1/8/2021	Supplemental Expert Report of Stephen C. Bergmeier, PH. D. Regarding Infringement by Apotex of U.S. Patent No. 10,071,977, With Exhibits and/or Attachments				
770	1/31/2020	Opening Expert Report of Daniel Combs Regarding Infringement, With Exhibits and/or Attachments				
771	12/21/2020	Opening Expert Report of Daniel Combs Regarding Infringement of U.S. Patent Nos. 10,376,487 and 10,449,176, With Exhibits and/or Attachments				
772	8/27/2021	Expert Report of Stephen C. Bergmeier, PH. D Regarding Infringement by Apotex of U.S. Patent Nos. 10,829,465 and 10,611,744, With Exhibits and/or Attachments				
773	8/27/2021	Expert Report of Stephen C. Bergmeier, PH. D Regarding Infringement by MSN of U.S. Patent Nos. 10,829,465 and 10,611,744, With Exhibits and/or Attachments				
774	8/27/2021	Expert Report of Stephen C. Bergmeier, PH. D Regarding Infringement by Teva of U.S. Patent Nos. 10,829,465 and 10,611,744, With Exhibits and/or Attachments				
775	8/27/2021	Expert Report of Daniel Combs, M.D. Regarding Infringement of U.S. Patent No. 10,610,511, With Exhibits and/or Attachments				

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

(C.A. No. 18-00651-CFC)

Vanda Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc., et al.

Plaintiff's Trial Exhibit List

<u>Exhibit Number</u>	<u>Date</u>	<u>Description</u>	<u>Beginning Bates Number</u>	<u>Ending Bates Number</u>	<u>Defendants' Objections</u>	<u>Admitted</u>
776	3/30/2020	Expert Report of Stephen C. Bergmeier, PH.D Regarding the Validity of U.S. Patent No. 10,071,977, With Exhibits and/or Attachments				
777	2/16/2021	Supplemental Expert Report of Stephen C. Bergmeier, PH.D Regarding the Validity of U.S. Patent No. 10,071,977, With Exhibits and/or Attachments				
778	3/30/2020	Expert Rebuttal Report of Charles A. Czeisler, With Exhibits and/or Attachments				
779	5/12/2020	Corrected Materials Considered for Report of Charles A. Czeisler				
780	3/30/2020	Expert Rebuttal Report of Dr. Steven W. Lockley, With Exhibits and/or Attachments				
781	5/12/2020	Corrected Materials Considered for Report of Steven W. Lockley				
782	3/30/2020	Expert Rebuttal Report of Andrew Parkinson, With Exhibits and/or Attachments				
783	5/12/2020	Corrected Expert Rebuttal Report of Andrew Parkinson, With Exhibits and/or Attachments				
784	5/12/2020	Corrected Materials Considered for Report of Andrew Parkinson				
785	3/30/2020	Expert Report of Henry G. Grabowski, With Exhibits and/or Attachments and/or Appendices				
786	2/16/2021	Expert Rebuttal Report of Charles A. Czeisler, With Exhibits and/or Attachments				
787	2/16/2021	Expert Rebuttal Report of Andrew Parkinson Regarding the Validity of U.S. Patent No. 10,376,487, With Exhibits and/or Attachments				

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

(C.A. No. 18-00651-CFC)

Vanda Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc., et al.

Plaintiff's Trial Exhibit List

<u>Exhibit Number</u>	<u>Date</u>	<u>Description</u>	<u>Beginning Bates Number</u>	<u>Ending Bates Number</u>	<u>Defendants' Objections</u>	<u>Admitted</u>
788	2/16/2021	Expert Report of Henry G. Grabowski, With Exhibits and/or Attachments and/or Appendices				
789	2/16/2021	Expert Report of Dr. Steven W. Lockley, With Exhibits and/or Attachments				
790	9/29/2021	Supplemental Rebuttal Report of Charles A. Czeisler, With Exhibits and/or Attachments				
791	9/29/2021	Supplemental Expert Report of Henry G. Grabowski, PH.D., With Exhibits and/or Attachments and/or Appendices				
792	9/29/2021	Supplemental Expert Report of Dr. Steven W. Lockley, With Exhibits and/or Attachments				
793	9/29/2021	Supplemental Expert Report of Stephen C. Bergmeier, PH.D Regarding the Validity of U.S. Patent No. 10,829,465, With Exhibits and/or Attachments				
794	8/14/2020	Reply Report of Daniel Combs, With Exhibits and/or Attachments				
795	11/1/2021	Reply Report of Stephen C. Bergmeier, PH.D. Regarding Infringement of U.S. Patent Nos. 10,071,977 and 10,829,465 by Apotex, With Exhibits				
796	11/1/2021	Reply Report of Stephen C. Bergmeier, PH.D. Regarding Infringement of U.S. Patent Nos. 10,071,977 and 10,829,465 by Teva, With Exhibits and/or Attachments				
797	11/1/2021	Reply Report of Stephen C. Bergmeier, PH.D. Regarding Infringement of U.S. Patent Nos. 10,071,977 and 10,829,465 by MSN, With Exhibits and/or Attachments				

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

(C.A. No. 18-00651-CFC)

Vanda Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc., et al.

Plaintiff's Trial Exhibit List

<u>Exhibit Number</u>	<u>Date</u>	<u>Description</u>	<u>Beginning Bates Number</u>	<u>Ending Bates Number</u>	<u>Defendants' Objections</u>	<u>Admitted</u>
798	2/23/2011	Protocol Registration Receipt NCT01163032: Efficacy and Safety of Tasimelteon Compared with Placebo in Totally Blind Subjects with Non-24-Hour Sleep-Wake Disorder	VNDHTLZ 00224327	VNDHTLZ 00224333		
799	6/16/2011	History of Changes for Study: NCT01163032: Efficacy and Safety of Tasimelteon Compared with Placebo in Totally Blind Subjects with Non-24-Hour Sleep-Wake Disorder				
800	8/30/2011	History of Changes for Study: NCT01163032: Efficacy and Safety of Tasimelteon Compared with Placebo in Totally Blind Subjects with Non-24-Hour Sleep-Wake Disorder				
801	7/29/2011	History of Changes for Study: NCT01163032: Efficacy and Safety of Tasimelteon Compared with Placebo in Totally Blind Subjects with Non-24-Hour Sleep-Wake Disorder				
802	6/8/2011	History of Changes for Study: NCT01163032: Efficacy and Safety of Tasimelteon Compared with Placebo in Totally Blind Subjects with Non-24-Hour Sleep-Wake Disorder				
803	11/7/2012	Study NCT01163032: Efficacy and Safety of Tasimelteon Compared with Placebo in Totally Blind Subjects with Non-24-Hour Sleep-Wake Disorder (version 23)	VNDHTLZ 03083672	VNDHTLZ 03083680		
804	6/28/2012	Study NCT01163032: Efficacy and Safety of Tasimelteon Compared with Placebo in Totally Blind Subjects with Non-24-Hour Sleep-Wake Disorder (version 21)	VNDHTLZ 03083662	VNDHTLZ 03083671		
805	11/7/2012	History of Changes for Study: NCT01163032: Efficacy and Safety of Tasimelteon Compared with Placebo in Totally Blind Subjects with Non-24-Hour Sleep-Wake Disorder				
806	2/23/2011	History of Changes for Study: NCT01163032: Efficacy and Safety of Tasimelteon Compared with Placebo in Totally Blind Subjects with Non-24-Hour Sleep-Wake Disorder				

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

(C.A. No. 18-00651-CFC)

Vanda Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc., et al.

<u>Plaintiff's Trial Exhibit List</u>						
<u>Exhibit Number</u>	<u>Date</u>	<u>Description</u>	<u>Beginning Bates Number</u>	<u>Ending Bates Number</u>	<u>Defendants' Objections</u>	<u>Admitted</u>
807	6/28/2012	History of Changes for Study: NCT01163032: Efficacy and Safety of Tasimelteon Compared with Placebo in Totally Blind Subjects with Non-24-Hour Sleep-Wake Disorder				
808	4/9/2014	[REDACTED]	VNDHTLZ 01067721	VNDHTLZ 01067751		

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

VANDA PHARMACEUTICALS
INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA,
INC., et al.,

Defendants.

C.A. No. 18-651-CFC
(Consolidated)

Exhibit 11 – Defendants’ Trial Exhibit List

Defendants' Trial Exhibit List

Ex. No.	Description	Doc Date	Beginning Bates	Ending Bates	Objections	Admitted
DTX-1	U.S. Patent No. 10,071,977	9/11/2018	VNDHTLZ 00010610	VNDHTLZ 00010620		
DTX-2	U.S. Patent No. 10,610,510	4/7/2020	VNDHTLZ 03100485	VNDHTLZ 03100519		
DTX-3	U.S. Patent No. 10,611,744	4/7/2020	VNDHTLZ 03101216	VNDHTLZ 03101225		
DTX-4	U.S. Patent No. 10,829,465	11/10/2020	VNDHTLZ 03101428 VNDHTLZ 03102467	VNDHTLZ 03101437 VNDHTLZ 03102476		
DTX-5	U.S. Patent No. 8,785,492	7/22/2014	VNDHTLZ 00000236	VNDHTLZ 00000269		
DTX-6	File history of U.S. Patent No. 10,610,510		VNDHTLZ 03099569	VNDHTLZ 03100484		
DTX-7	File history of U.S. Patent No. 10,611,744		VNDHTLZ 03100649	VNDHTLZ 03101215		
DTX-8	File history of U.S. Patent No. 10,829,465		VNDHTLZ 03101226	VNDHTLZ 03101427		
DTX-9	Badyal and A.P. Dadhich, "Cytochrome P450 and Drug Interactions," Indian Journal of Pharmacology, 33:248-259 (2001) ("Badyal")	2001	TASI-DEF-0000207	TASI-DEF-0000218		
DTX-10	K.E. Culm-Merdek et al., "Fluvoxamine impairs single-dose caffeine clearance without altering caffeine pharmacodynamics," British Journal of Clinical Pharmacology, 60(5):486-493 (2005)	2005	TASI-DEF-0001525	TASI-DEF-0001532		
DTX-11	G. Facciola et al., "Cytochrome P 450 isoforms involved in melatonin metabolism in human liver microsomes," Pharmacokinetics and Disposition, 56:881-888 (2001) ("Facciola")	2001	TASI-DEF-0001533	TASI-DEF-0001540		
DTX-12	D. Farkas et al., Mechanisms and consequences of drug-drug interactions. In: Gad SC, ed. Preclinical Development Handbook: ADME and Biopharmaceutical Properties. Philadelphia: Wiley-Interscience; 879-917 (2008)	2008	TASI-DEF-0001541	TASI-DEF-0001579		
DTX-13	M.T. Granfors et al., "Fluvoxamine drastically increases concentrations and effects of tizanidine: a potentially hazardous interaction. <i>Clin Pharmacol Ther</i> . 75(4):331-341 (2004)	2004	TASI-DEF-0001580	TASI-DEF-0001590		
DTX-14	D.J. Greenblatt et al., "Age and Gender Effects on the Pharmacokinetics and Pharmacodynamics of Ramelteon, a Hypnotic Agent Activating via Melatonin receptors MT 1 and MT 2," The Journal of Clinical Pharmacology, 47(4):485-496 (2007) ("Greenblatt")	2007	TASI-DEF-0001591	TASI-DEF-0001603		
DTX-15	D.J. Greenblatt et al., The CYP3 family. In: Ioannides C, ed. Cytochrome P450: Role in the Metabolism and Toxicology of Drugs and Other Xenobiotics. Cambridge (UK): Royal Society of Chemistry; 354-383 (2008)	2008	TASI-DEF-0001604	TASI-DEF-0001633		

Defendants' Trial Exhibit List

Ex. No.	Description	Doc Date	Beginning Bates	Ending Bates	Objections	Admitted
DTX-16	R. Hardeland, "Tasimelteon, a melatonin agonist for the treatment of insomnia and circadian rhythm sleep disorders," Current Opinion in Investigational Drugs, 10(7):691-701 (2009) ("Hardeland")	2009	TASI-DEF-0000138	TASI-DEF-0000148		
DTX-17	R. Hardeland, "Investigational melatonin receptor agonist," Expert Opinion on Investigational Drugs, 19(6):747-764 (2010) ("Hardeland 2010")	2010	TASI-DEF-0001677	TASI-DEF-0001695		
DTX-18	U. Jeppesen et al., "A fluvoxamine-caffeine interaction study" Pharmacogenetics, 6:213-222 (1996)	1996	TASI-DEF-0001696	TASI-DEF-0001705		
DTX-19	A. Karim et al., "Disposition kinetics and tolerance of escalating single doses of ramelteon, a high-affinity MT1 and MT2 melatonin receptor agonist indicated for treatment of insomnia," J Clin Pharmacol, 46(2):140-148 (2006)	2006	TASI-DEF-0001706	TASI-DEF-0001715		
DTX-20	D.A. Lankford, "Tasimelteon for insomnia," Expert Opinion on Investigational Drugs, 20(7): 987-993 (2011) ("Lankford")	2011	TASI-DEF-0000154	TASI-DEF-0000161		
DTX-21	Albert P. Li, In Vitro Evaluation of Metabolic Drug-Drug Interactions: Concepts and Practice, in Drug-Drug Interactions in Pharmaceutical Development (Albert P. Li ed., 2007) ("Li")		TASI-DEF-0001716	TASI-DEF-0001754		
DTX-22	X. Ma et al., "Metabolism of Melatonin by Human Cytochromes P450," Drug Metabolism and Disposition, 33(4):489-494 (2005) ("Ma")	2005	TASI-DEF-0001755	TASI-DEF-0001760		
DTX-23	L.G. Miller et al, "Kinetics, brain uptake, and receptor binding characteristics of flurazepam and its metabolites" Psychopharmacology (Berl) 94(3):386-391 (1988)	1988	TASI-DEF-0001761	TASI-DEF-0001766		
DTX-24	C.C. Ogu and J.L. Maxa, "Drug Interactions due to cytochrome P450," BUMC Proceedings, 13:421-423 (2000) ("Ogu")	2000	TASI-DEF-0000110	TASI-DEF-0000112		
DTX-25	S.M.W. Rajaratnam et al., "Melatonin agonist tasimelteon (VEC-162) for transient insomnia after sleep-time shift: two randomized controlled multicenter trials," Lancet, 373:482-91 (2009) ("Rajaratnam")	2009	TASI-DEF-0000162 VNDHTLZ 02026452	TASI-DEF-0000171 VNDHTLZ 02026461		
DTX-26	D. Simpson and M. P. Curran, "Ramelteon A Review of Its Use in Insomnia," Drugs, 68(1):1901-1919 (2008) ("Simpson")	2008	TASI-DEF-0001792	TASI-DEF-0001810		
DTX-27	R. Torres et al., "Pharmacokinetics of the Dual Melatonin Receptor Agonist Tasimelteon in Subjects with Hepatic and Renal Impairment," Journal of Clinical Pharmacology, 55(5):525-533 (2015) ("Torres")	2015	TASI-DEF-0001825	TASI-DEF-0001833		

Defendants' Trial Exhibit List

Ex. No.	Description	Doc Date	Beginning Bates	Ending Bates	Objections	Admitted
DTX-28	L.L. von Moltke and D.J. Greenblatt, Clinical drug interactions due to metabolic inhibition: Prediction, assessment, and interpretation. In: Lu C, Li AP, eds. Enzyme Inhibition in Drug Discovery and Development. Hoboken NJ: John Wiley & Sons; 533-547 (2010)	2010	TASI-DEF-0001834	TASI-DEF-0001848		
DTX-29	J.B. Zawilska et al., "Physiology and pharmacology of melatonin in relation to biological rhythms," Pharmacological Reports, 61:381-410 (2009) ("Zawilska")	2009	TASI-DEF-0000054	TASI-DEF-0000081		
DTX-30	https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/205677Orig1s000ClinPharmR.pdf ("FDA data")					
DTX-31	Vanda Meeting Request with FDA re Type B, End of Phase-2 Meeting	10/8/2010	VNDHTLZ 00014544	VNDHTLZ 00014549		
DTX-32	Email from Paolo Baroldi to Mihael H. Polymeropoulos attaching Briefing Documents for FDA Advisory Committee Meeting re Tasimelteon NDA 205,677	9/15/2013	VNDHTLZ 00963062	VNDHTLZ 00963139		
DTX-33	J. Arendt and S. M. W. Rajaratnam, "Melatonin and Its Agonists: An Update," The British Journal of Psychiatry, 193:267-269 (2008)	2008	TASI-DEF-0001359	TASI-DEF-0001361		
DTX-34	M. Choy and R.L. Salbu, Jet Lag: "Current and Potential Therapies," Pharmacy and Therapeutics, 36(4):221-231 (2011)	2011	TASI-DEF-0000243	TASI-DEF-0000247		
DTX-35	H. R. Colten and B. M. Altevogt, "Sleep Disorders and Sleep Deprivation: An Unmet Public Health Problem," Washington, DC: Institute of Medicine (2006)	2006	TASI-DEF-0001849	TASI-DEF-0001852		
DTX-36	R. Hardeland, "New Approaches in the Management of Insomnia: Weighing the Advantages of Prolonged-Release Melatonin and Synthetic Melatoninergeric Agonists," Neurophysyciatric Disease and Treatment, 5:341-354 (2009)	2009	TASI-DEF-0000124 VNDHTLZ 02468054	TASI-DEF-0000137		
DTX-37	Morgenthaler et al., "Practice Parameters for the Clinical Evaluation and Treatment of Circadian Rhythm Sleep Disorders," Sleep, 30(11):1445-1459 (2007)	2007	TASI-DEF-0001510 VNDHTLZ 02215998	TASI-DEF-0001524		
DTX-38	Salva et al., "Circadian Rhythms, Melatonin and Depression," Current Pharmaceutical Design, 17:1459-1470 (2011)	2011	TASI-DEF-0001408	TASI-DEF-0001419		
DTX-39	D.J. Skene and J. Arendt, "Circadian Rhythm Sleep Disorders in the Blind and their Treatment with Melatonin," Sleep Medicine, 8:651-655 (2007)	2007	TASI-DEF-0000149	TASI-DEF-0000153		

Defendants' Trial Exhibit List

Ex. No.	Description	Doc Date	Beginning Bates	Ending Bates	Objections	Admitted
DTX-40	Nava Zisapel, "Circadian Rhythm Sleep Disorders: Pathophysiology and Potential Approaches to Management," CNS Drugs, 15(4):311-328 (2001)	2001	TASI-DEF-0001454	TASI-DEF-0001471		
DTX-41	WO 2007/137244	11/29/2007	VNDHTLZ 02585388 TASI-DEF-0001362	VNDHTLZ 02585416 TASI-DEF-0001388		
DTX-42	ClinicalTrials.gov Identifier: NCT01163032, Efficacy and Safety of Tasimelteon Compared with Placebo in Totally Blind Subjects With Non-24-Hour Sleep-Wake Disorder, July 15, 2010	7/15/2010	TASI-DEF-0000679 TASI-DEF-0001472	TASI-DEF-0000686 TASI-DEF-0001509		
DTX-43	Vanda 2010 10-K		TASI-DEF-0001949	TASI-DEF-0002173		
DTX-44	U.S. Provisional Appl. 62/087,394		VNDHTLZ 00010785	VNDHTLZ 00010816		
DTX-45	U.S. Provisional Appl. 61/938,932		VNDHTLZ 00010837	VNDHTLZ 00010864		
DTX-46	U.S. Patent Pub. No. 2010/0298584		TASI-DEF-0001942	TASI-DEF-0001948		
DTX-47	BMS Scientific Report, May 1, 2000	5/1/2000	VNDHTLZ 00014257	VNDHTLZ 00014291		
DTX-48	IND 54,776, Vol. 11		VNDHTLZ 00041937	VNDHTLZ 00042300		
DTX-49	BMS, Photostability of BMS-214778 Drug Substance		VNDHTLZ 00044521	VNDHTLZ 00044527		
DTX-50	Bari et al., "Impurity Profile: Significance in Active Pharmaceutical Ingredient," Eurasian J. of Analytical Chem., 2(1):32-53 (2007)	2007	TASI-DEF-0000786	TASI-DEF-0000807		
DTX-51	Prasad et al., "Development of Jacobsen Asymmetric Epoxidation and Sharpless Asymmetric Dihydroxylation Methods for the Large-Scale Preparation of a Chiral Dihydrobenzofuran Epoxide," Organic Process Research & Development, 7:821-827 (2003)	2003	TASI-DEF-0000907	TASI-DEF-0000913		
DTX-52	A.K. Singh et al., "Factors Influencing the Application of Literature Methods Toward the Preparation of a Chiral trans-Cyclopropane Carboxylic Acid Intermediate During Development of a Melatonin Agonist," in Asymmetric Catalysis on Industrial Scale: Challenges, Approaches and Solutions 335-348 (H.U. Blaser and E. Schmidt eds., 2004) ("Singh")	2004	TASI-DEF-0001811	TASI-DEF-0001824		
DTX-53	FDA Guidance for Industry, "Manufacturing, Processing, or Holding Active Pharmaceutical Ingredients" (March 1998)	Mar. 1998	TASI-DEF-0000837	TASI-DEF-0000893		
DTX-54	ICH Q3A Guideline		TASI-DEF-0001201	TASI-DEF-0001217		
DTX-55	ICH Q3A(R2) Guideline	10/25/2006	TASI-DEF-0001333	TASI-DEF-0001347		
DTX-56	ICH Q6A Guideline		TASI-DEF-0001064	TASI-DEF-0001109		

Defendants' Trial Exhibit List

Ex. No.	Description	Doc Date	Beginning Bates	Ending Bates	Objections	Admitted
DTX-57	Ralph L. Shriner et al., "The Systematic Identification of Organic Compounds: A Laboratory Manual," 114-15 (John Wiley & Sons, Inc., 5th ed. 1964)	1964	TASI-DEF-0001937	TASI-DEF-0001941		
DTX-58	Piia Hara et al., "Sol-gels and cross-linked aggregates of lipase PS from Burkholderia cepacia and their application in dry organic solvents," Journal of Molecular Catalysis B: Enzymatic, 50.2-4:80-86 (2008)	2008	TASI-DEF-0001907	TASI-DEF-0001913		
DTX-59	Federal Register 65(251): 83041-63 (Dec. 29, 2000)	12/29/2000	TASI-DEF-0001884	TASI-DEF-0001906		
DTX-60	Vanda Pharmaceutical Press Release, Nov. 14, 2013	11/14/2013	VNDHTLZ 00257192	VNDHTLZ 00257194		
DTX-61	Vanda Pharmaceutical Press Release, May 31, 2013	5/31/2013	VNDHTLZ 00937032	VNDHTLZ 00937033		
DTX-62	Garde, Damian (2013, November 15) FDA Advisory Committee Recommends Approval of Hetlioz™ for the Treatment of Non-24-Hour-Disorder (Non-24) in the Totally Blind. Retrieved from https://www.fiercebiotech.com/biotech/fda-advisory-committee-recommends-approval-of-hetlioz%E2%84%A2-for-treatment-of-non-24-hour		TASI-DEF-0001879	TASI-DEF-0001883		
DTX-63	May 8, 2012 Vanda Website, retrieved from https://web.archive.org/web/2012050810453pharma.com/devtasimelteon.html		TASI-DEF-0001048			
DTX-64	"Efficacy and Safety of Tasimelteon Compared With Placebo in Totally Blind Subjects With Non 24-Hour Sleep-Wake Disorder," NTC01163032 (July 15, 2010)	7/15/2010	TASI-DEF-0000082 TASI-DEF-0000181	TASI-DEF-0000090 TASI-DEF-0000191		
DTX-65	March 28, 2013 Vanda website, retrieved from https://web.archive.org/web/20130328210129/http://www.vandapharma.com/		TASI-DEF-0001006			
DTX-66	IND 54,766, Vol. 3		VNDHTLZ 00042301	VNDHTLZ 00042430		
DTX-67	BMS Analytical Method Summary Report, June 30, 1997	6/30/1997	VNDHTLZ 00077433	VNDHTLZ 00077441		
DTX-68	BMS Analytical Method Summary Report, Sept. 30, 1997	9/30/1997	VNDHTLZ 00077452	VNDHTLZ 00077457		
DTX-69	BMS LC/MS Profiling of Metabolites in Human Intestine S-9 Incubated with BMS-214778		VNDHTLZ 00078491	VNDHTLZ 00078492		
DTX-70	QPS Amended Bioanalytical Sample Analysis Report		VNDHTLZ 00102049	VNDHTLZ 00102647		

Defendants' Trial Exhibit List

Ex. No.	Description	Doc Date	Beginning Bates	Ending Bates	Objections	Admitted
DTX-71	License, Development and Commercialization Agreement by and between BMS and Vanda		VNDHTLZ 00977439	VNDHTLZ 00977495		
DTX-72	Email from Natalie Platt	5/6/2013	VNDHTLZ 01024459	VNDHTLZ 01024460		
DTX-73	Vanda NDA 205677, § 3.2.S.3.2		VNDHTLZ 01101238	VNDHTLZ 01101260		
DTX-74	BMS Certificate of Analysis		VNDHTLZ 00023734			
DTX-75	BMS Certificate of Analysis		VNDHTLZ 00042663			
DTX-76	BMS Certificate of Analysis		VNDHTLZ 00023745	VNDHTLZ 00023757		
DTX-77	BMS Certificate of Analysis		VNDHTLZ 00079886	VNDHTLZ 00079888		
DTX-78	PWG, "Melatonin Agonist," Neuroscience		VNDHTLZ 01717277	VNDHTLZ 01717439		
DTX-79	NDA 205677, § 2.3.S.2.2		VNDHTLZ 00255689	VNDHTLZ 00255739		
DTX-80	NDA 205677, § 2.3.S.3		VNDHTLZ 01100696	VNDHTLZ 01100724		
DTX-81	NDA 205677, § 3.2.S.2.2		VNDHTLZ 00255872	VNDHTLZ 00255926		
DTX-82	NDA 205677, § 3.2.S.2.6		VNDHTLZ 01125156	VNDHTLZ 01125186		
DTX-83	NDA 205677, § 3.2.S.3.2		VNDHTLZ 01101238	VNDHTLZ 01101260		
DTX-84	Email from Deepak Phadke	10/12/2011	VNDHTLZ 01002953			
DTX-85	NDA 205677, § 3.2.S.4.4		VNDHTLZ 01022660	VNDHTLZ 01022690		
DTX-86	NDA 205677, § 3.2.S.2.6 (draft)		VNDHTLZ 01024384	VNDHTLZ 01024413		
DTX-87	NDA 205677, § 3.2.P.2.2		VNDHTLZ 00394126	VNDHTLZ 00394150		
DTX-88	NDA 205677, § 3.2.P.8.3		VNDHTLZ 00810070	VNDHTLZ 00810114		
DTX-89	NDA 205677, Correspondence		VNDHTLZ 00569302	VNDHTLZ 00569450		
DTX-90	Vanda Pre-NDA CMC Meeting Briefing Book		VNDHTLZ 00043983	VNDHTLZ 00044092		
DTX-91	Email from Maurice Baillargeon	11/27/2013	VNDHTLZ 01036406			
DTX-92	Vanda Open Purchase Order List		VNDHTLZ 02920622	VNDHTLZ 02920785		
DTX-93	[REDACTED]		VNDHTLZ 03080705	VNDHTLZ 03080713		
DTX-94	[REDACTED], email attachment		VNDHTLZ 01036407			
DTX-95	[REDACTED]		VNDHTLZ 03080676	VNDHTLZ 03080687		
DTX-96	[REDACTED]		VNDHTLZ 01016830	VNDHTLZ 01016855		
DTX-97	Quality Agreement for [REDACTED] between Vanda and [REDACTED]		VNDHTLZ 03080689	VNDHTLZ 03080704		
DTX-98	[REDACTED]		VNDHTLZ 01036408	VNDHTLZ 01036418		
DTX-99	[REDACTED]	12/5/2013	VNDHTLZ 01036636	VNDHTLZ 01036637		
DTX-100	[REDACTED]		VNDHTLZ 01036638	VNDHTLZ 01036640		
DTX-101	[REDACTED]	12/6/2013	VNDHTLZ 01036646	VNDHTLZ 01036649		

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Ex. No.	Description	Doc Date	Beginning Bates	Ending Bates	Objections	Admitted
DTX-102	[REDACTED]		VNDHTLZ 01036650	VNDHTLZ 01036652		
DTX-103	[REDACTED]		VNDHTLZ 01037028	VNDHTLZ 01037029		
DTX-104	[REDACTED]		VNDHTLZ 01037030	VNDHTLZ 01037031		
DTX-105	[REDACTED]		VNDHTLZ 01037036	VNDHTLZ 01037037		
DTX-106	[REDACTED]		VNDHTLZ 02637170	VNDHTLZ 02637171		
DTX-107	[REDACTED]		VNDHTLZ 02637455	VNDHTLZ 02637467		
DTX-108	IND 54,776, Information Amendment SN 0156		VNDHTLZ 01101929	VNDHTLZ 01101960		
DTX-109	IND 54, 776 - Serial No. 164	5/1/2012	VNDHTLZ 01202715	VNDHTLZ 01202882		
DTX-110	Email from Natalie Platt	1/6/2012	VNDHTLZ 01103377	VNDHTLZ 01103378		
DTX-111	Project Completion Schedule spreadsheet		VNDHTLZ 01103379			
DTX-112	[REDACTED]		VNDHTLZ 01106715	VNDHTLZ 01106722		
DTX-113	[REDACTED]		VNDHTLZ 02677712	VNDHTLZ 02677784		
DTX-114	Batch Record F199F-11001		VNDHTLZ 02969930	VNDHTLZ 02969962		
DTX-115	Batch Record F199F-12001		VNDHTLZ 02970030	VNDHTLZ 02970083		
DTX-116	Batch Record F199F-13001, Translation		VNDHTLZ 01179777 TASI-DEF-TRANSLATION-0000001	VNDHTLZ 01179902 TASI-DEF-TRANSLATION-0000127		
DTX-117	Batch Record F199-13001		VNDHTLZ 03081571	VNDHTLZ 03081665		
DTX-118	Batch Record F199-13003 and Translation		VNDHTLZ 01180911 TASI-DEF-TRANSLATION-0000213	VNDHTLZ 01180998 TASI-DEF-TRANSLATION-0000301		
DTX-119	Batch Record F199F-13003 and Translation		VNDHTLZ 01181077 TASI-DEF-TRANSLATION-0000381	VNDHTLZ 01181112 TASI-DEF-TRANSLATION-0000417		
DTX-120	Batch Record F199F-13003 and Translation		VNDHTLZ 01182876 TASI-DEF-TRANSLATION-0000450	VNDHTLZ 01182941 TASI-DEF-TRANSLATION-0000516		
DTX-121	Batch Record F199-13004 and Translation		VNDHTLZ 02956122 TASI-DEF-TRANSLATION-0000302	VNDHTLZ 02956199 TASI-DEF-TRANSLATION-0000380		
DTX-122	Batch Record F199F-13004 and Translation		VNDHTLZ01182942 TASI-DEF-TRANSLATION-0000517	VNDHTLZ01183005 TASI-DEF-TRANSLATION-0000581		

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Ex. No.	Description	Doc Date	Beginning Bates	Ending Bates	Objections	Admitted
DTX-123	Batch Record F199F-13004 and Translation		VNDHTLZ01181113 TASI-DEF-TRANSLATION-0000418	VNDHTLZ01181143 TASI-DEF-TRANSLATION-0000449		
DTX-124	Batch Record F199-13002 and Translation		VNDHTLZ02974275 TASI-DEF-TRANSLATION-0000128	VNDHTLZ02974358 TASI-DEF-TRANSLATION-0000212		
DTX-125	Email from Natalie Platt	12/5/2014	VNDHTLZ01018456	VNDHTLZ01018458		
DTX-126	Vanda Tasimelteon (VEC-162) Program Update, 2007		VNDHTLZ02904925	VNDHTLZ02904954		
DTX-127	[REDACTED]		VNDHTLZ03081547	VNDHTLZ03081561		
DTX-128	Cipro® Label		TASI-DEF-0002248	TASI-DEF-0002300		
DTX-129	Rifadin® Label		TASI-DEF-0002470	TASI-DEF-0002487		
DTX-130	Verelan® Label		TASI-DEF-0002519	TASI-DEF-0002527		
DTX-131	Calan® Label		TASI-DEF-0002233	TASI-DEF-0002247		
DTX-132	Luvox® Label		TASI-DEF-0002327	TASI-DEF-0002358		
DTX-133	Rozerem® Label		TASI-DEF-0002488	TASI-DEF-0002503		
DTX-134	Ambien® Label		TASI-DEF-0002211	TASI-DEF-0002232		
DTX-135	Lunesta® Label		TASI-DEF-0002301	TASI-DEF-0002326		
DTX-136	Sonata® Label		TASI-DEF-0002504	TASI-DEF-0002518		
DTX-137	2018 Vanda Pharmaceuticals Inc. Form 10-K		TASI-DEF-0002359	TASI-DEF-0002469		
DTX-138	VP-VEC-162-2101 (SET) 2010 Study Protocol		VNDHTLZ 01915922	VNDHTLZ 01915927		
DTX-139	Draft Hetlioz Label		VNDHTLZ 00392390	VNDHTLZ 00392405		
DTX-140	Email from Mihael H. Polymeropoulos to FDA re Vanda's response on FDA meeting denial and subpart H proposal IND 54,776	5/3/2012	VNDHTLZ 02985513	VNDHTLZ 02985514		
DTX-141	https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved					
DTX-142	https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM387652.pdf					
DTX-143	https://www.fda.gov/patients/learn-about-drug-and-device-approvals/drug-development-process					
DTX-144	https://www.fda.gov/patients/drug-development-process/step-1-discovery-and-development					
DTX-145	https://www.fda.gov/patients/drug-development-process/step-2-preclinical-research					

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Ex. No.	Description	Doc Date	Beginning Bates	Ending Bates	Objections	Admitted
DTX-146	https://www.fda.gov/patients/drug-development-process/step-3-clinical-research					
DTX-147	https://www.fda.gov/patients/drug-development-process/step-4-fda-drug-review					
DTX-148	https://www.fda.gov/media/72297/download					
DTX-149	https://www.fda.gov/media/97618/download					
DTX-150			APO-TASI-0008790	APO-TASI-0009152		
DTX-151	Daniel P. Cardinali and Diego A. Golombek, "Let there be sleep—on time," 373 LANCET 9662:439-41 (2009)	2009	TASI-DEF-0014800	TASI-DEF-0014802		
DTX-152	Emens et al., "Relative Coordination to Unknown "Weak Zeitgebers" in Free-Running Blind Individuals," 20 J. OF BIOLOGICAL RHYTHMS, 2:159-67 (2005)	2005	TASI-DEF-0020193	TASI-DEF-0020201		
DTX-153	Emens et al., "The Rest/Activity Cycle and the Melatonin Rhythm in Blind Free-runners Have Similar Periods," 25 J. OF BIOLOGICAL RHYTHMS 5:381-84 (2010)	2010	TASI-DEF-0020202	TASI-DEF-0020205		
DTX-154	Lewy et al., "Pretreatment circadian period in free-running blind people may predict the phase angle of entrainment to melatonin," 313 NEUROSCIENCE LETTERS 3:158-60 (2001)	2001	VNDHTLZ 03082622	VNDHTLZ 03082624		
DTX-155	Lewy et al., "Eventual entrainment of the human circadian pacemaker by melatonin is independent of the circadian phase of treatment initiation: Clinical implications," 19 J. OF BIOLOGICAL RHYTHMS 1:68-75 (2004)	2004	VNDHTLZ 02587680	VNDHTLZ 02587687		
DTX-156	Lewy et al., "Melatonin entrains free-running blind people according to a physiological dose-response curve," 22 CHRONOBIOLOGY INT'L 6:1093-1106 (2005)	2005	VNDHTLZ 03083113	VNDHTLZ 03083126		
DTX-157	Roth et al., "Prolonged release melatonin for improving sleep in totally blind subjects: A pilot placebo-controlled multicenter trial," NATURE AND SCI. OF SLEEP 7:13-23 (2015)	2015	TASI-DEF-0015132	TASI-DEF-0015142		
DTX-158	Vanda November 2010 10-Q		TASI-DEF-0020082	TASI-DEF-0020122		
DTX-159	NATIONAL SLEEP FOUNDATION, "Non 24 Sleep Wake Disorder Treatment and Care," https://www.sleepfoundation.org/non-24-sleep-wake-disorder/treatment-care (last visited August 4, 2020)		TASI-DEF-0020182	TASI-DEF-0020187		
DTX-160	CIRCADIAN SLEEP DISORDERS NETWORK, "Non-24-Hour Sleep Wake Disorder Questions & Answers," https://www.circadiansleepdisorders.org/docs/N24-QandA.php (last visited August 4, 2020)		TASI-DEF-0020178	TASI-DEF-0020181		

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Ex. No.	Description	Doc Date	Beginning Bates	Ending Bates	Objections	Admitted
DTX-161	SLEEP MEDICINE, "Non-24-Hour Sleep-Wake Rhythm – Diagnosis & Treatment," http://sleepeducation.org/sleep-disorders-by-category/circadian-rhythm-disorders/non-24-hour-sleep-wake-rhythm/diagnosis-treatment (last visited August 4, 2020)		TASI-DEF-0020188	TASI-DEF-0020189		
DTX-162	J.T. Backman et al., "Rifampicin is only a weak inducer of CYP1A2-mediated presystemic and systemic metabolism: studies with tizanidine and caffeine," <i>Eur J Clin Pharmacol</i> , 62(6):451-461 (2006) ("Backman")	2006	TASI-DEF-0003083	TASI-DEF-0003093		
DTX-163	S.M. Borcharding et al., "Two- and four-day rifampin chemoprophylaxis regimens induce oxidative metabolism," <i>Antimicrob Agents Chemother</i> , 36(7):1553-1558 (1992) ("Borcharding")	1992	TASI-DEF-0003353	TASI-DEF-0003358		
DTX-164	L.A. Kroon, "Drug interactions with smoking," <i>Am J Health Syst Pharm</i> , 64(18):1917-1921 (2007) ("Kroon")	2007	TASI-DEF-0014795	TASI-DEF-0014799		
DTX-165	H.R. Ochs et al., "Lack of influence of cigarette smoking on triazolam pharmacokinetics," <i>Br J Clin Pharmacol</i> , 23:759-763 (1987) ("Ochs")	1987	TASI-DEF-0015143	TASI-DEF-0015147		
DTX-166	E.E. Ohnhaus et al., "Enzyme-inducing drug combinations and their effects on liver microsomal enzyme activity in man," <i>Eur J Clin Pharmacol</i> , 24(2):247-250 (1983) ("Ohnhaus")	1983	TASI-DEF-0015156	TASI-DEF-0015159		
DTX-167	J.E. Sharer and S.A. Wrighton, "Identification of the human hepatic cytochromes P450 involved in the in vitro oxidation of antipyrine," <i>Drug Metab Dispos.</i> , 24(4):487-494 (1996) ("Sharer")	1996	TASI-DEF-0017966	TASI-DEF-0017973		
DTX-168	M.W. Teunissen et al., "Influence of rifampicin treatment on antipyrine clearance and metabolite formation in patients with tuberculosis," <i>Br J Clin Pharmacol</i> , 18(5):701-706 (1984) ("Teunissen")	1984	TASI-DEF-0017977	TASI-DEF-0017982		
DTX-169	K. Villikka et al., "Triazolam is ineffective in patients taking rifampin," <i>Clinical Pharmacology and Therapeutics</i> , 61:8-14 (1997) ("Villikka")	1997	TASI-DEF-0020158	ASI-DEF-0020164		
DTX-170	American Psychiatric Association, "What Is Depression?," https://www.psychiatry.org/patients-families/depression/what-is-depression (accessed 3/24/2020)	3/24/2020	TASI-DEF-0003042	TASI-DEF-0003044		

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Ex. No.	Description	Doc Date	Beginning Bates	Ending Bates	Objections	Admitted
DTX-171	BCBS of Massachusetts, "Pharmacy Medical Policy: Hetlioz (tasimelteon)," https://www.bluecrossma.com/common/en_US/medical_policies/697%20HETLIOZ%20tasimelteon%20prn.pdf (accessed 7/9/2020)	7/9/2020	TASI-DEF-0003146	TASI-DEF-0003148		
DTX-172	Case No. 19-1108 (E.D.N.Y.), D.I. 1 Complaint filed February 25, 2019	2/25/2019	TASI-DEF-0002996	TASI-DEF-0003037		
DTX-173	Case No. 19-1701-CFC (D. Del.), D.I. 1 Complaint filed September 11, 2019	9/11/2019	TASI-DEF-0002879	TASI-DEF-0002995		
DTX-174	ClinicalTrials.gov, "Trial record for VP-VEC-162-1105," https://clinicaltrials.gov/ct2/show/NCT01271387?term=VP-VEC-162-1105&draw=2&rank=1	2/17/2014	TASI-DEF-0003682	TASI-DEF-0003688		
DTX-175	ClinicalTrials.gov, "Trial record for VP-VEC-162-1106," https://clinicaltrials.gov/ct2/show/NCT01526746?term=VP-VEC-162-1106&draw=1&rank=1	2/17/2014	TASI-DEF-0003689	TASI-DEF-0003697		
DTX-176	ClinicalTrials.gov, "Trial record for VP-VEC-162-1107," https://clinicaltrials.gov/ct2/show/NCT01477619?term=VP-VEC-162-1107&draw=2&rank=1	2/17/2014	TASI-DEF-0003698	TASI-DEF-0003705		
DTX-177	ClinicalTrials.gov, "Trial record for VP-VEC-162-1108," https://clinicaltrials.gov/ct2/show/NCT01578057?term=VP-VEC-162-1108&draw=2&rank=1	2/17/2014	TASI-DEF-0003706	TASI-DEF-0003714		
DTX-178	ClinicalTrials.gov, "Trial record for VP-VEC-162-1110," https://clinicaltrials.gov/ct2/show/NCT01402076?term=VP-VEC-162-1110&draw=2&rank=1	2/17/2014	TASI-DEF-0003715	TASI-DEF-0003722		
DTX-179	ClinicalTrials.gov, "Trial record for VP-VEC-162-1111," https://clinicaltrials.gov/ct2/show/NCT01540500?term=VP-VEC-162-1111&draw=2&rank=1	2/17/2014	TASI-DEF-0003723	TASI-DEF-0003729		
DTX-180	ClinicalTrials.gov, "Trial record for VP-VEC-162-1112," https://clinicaltrials.gov/ct2/show/NCT01637636?term=VP-VEC-162-1112&draw=2&rank=1	2/17/2014	TASI-DEF-0003730	TASI-DEF-0003736		
DTX-181	ClinicalTrials.gov, "Trial record for VP-VEC-162-2101," https://clinicaltrials.gov/ct2/show/NCT00490945?term=VP-VEC-162-2101&draw=2&rank=1	8/26/2014	TASI-DEF-0003737	TASI-DEF-0003742		
DTX-182	ClinicalTrials.gov, "Trial record for VP-VEC-162-3101," https://clinicaltrials.gov/ct2/show/NCT00291187?term=VP-VEC-162-3101&draw=2&rank=1	10/15/2014	TASI-DEF-0003743	TASI-DEF-0003749		

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Ex. No.	Description	Doc Date	Beginning Bates	Ending Bates	Objections	Admitted
DTX-183	ClinicalTrials.gov, "Trial record for VP-VEC-162-3104," https://clinicaltrials.gov/ct2/show/NCT00548340?term=VP-VEC-162-3104&draw=2&rank=1	10/15/2014	TASI-DEF-0003750	TASI-DEF-0003757		
DTX-184	ClinicalTrials.gov, "Trial record for VP-VEC-162-3201," https://clinicaltrials.gov/ct2/show/NCT01163032?term=VP-VEC-162-3201&draw=2&rank=1	10/16/2014	TASI-DEF-0003758	TASI-DEF-0003767		
DTX-185	ClinicalTrials.gov, "Trial record for VP-VEC-162-3202," https://clinicaltrials.gov/ct2/show/NCT01218789?term=VP-VEC-162-3202&draw=1&rank=1	11/17/2017	TASI-DEF-0003768	TASI-DEF-0003775		
DTX-186	ClinicalTrials.gov, "Trial record for VP-VEC-162-3203," https://clinicaltrials.gov/ct2/show/NCT01430754?term=VP-VEC-162-3203&draw=2&rank=1	10/10/2014	TASI-DEF-0003776	TASI-DEF-0003784		
DTX-187	ClinicalTrials.gov, "Trial record for VP-VEC-162-3204," https://clinicaltrials.gov/ct2/show/NCT01429116?term=VP-VEC-162-3204&draw=2&rank=1	4/21/2015	TASI-DEF-0003785	TASI-DEF-0003792		
DTX-188	Cowen and Company, Therapeutic Categories Outlook, 9/28/2015	9/28/2015	TASI-DEF-0002850	TASI-DEF-0002860		
DTX-189	DiMasi, Feldman, Seckler, and Wilson (2010), "Trends in Risks Associated with New Drug Development: Success Rates for Investigational Drugs," Clinical Pharmacology & Therapeutics 87(3):272-277	2010	TASI-DEF-0003878	TASI-DEF-0003883		
DTX-190	DiMasi, Joseph et al. (1991), "Cost of Innovation in the Pharmaceutical Industry," Journal of Health Economics 10:107-142	1991	TASI-DEF-0003793	TASI-DEF-0003828		
DTX-191	DiMasi, Joseph, Ronald Hansen, and Henry Grabowski (2003), "The Price of Innovation: New Estimates of Drug Development Costs," Journal of Health Economics 22:151-185	2003	TASI-DEF-0003829	TASI-DEF-0003863		
DTX-192	FDA Orange Book Website, Patent and Exclusivity for: N205677, https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=205677&Appl_type=N (accessed 8/7/2020)	8/7/2020	TASI-DEF-0014204	TASI-DEF-0014205		
DTX-193	FDA Orange Book, 2014	2014	TASI-DEF-0003966	TASI-DEF-0005196		
DTX-194	FDA Orange Book, 2015	2015	TASI-DEF-0005197	TASI-DEF-0006476		
DTX-195	FDA Orange Book, 2016	2016	TASI-DEF-0006477	TASI-DEF-0007796		

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Ex. No.	Description	Doc Date	Beginning Bates	Ending Bates	Objections	Admitted
DTX-196	FDA Orange Book, 2017	2017	TASI-DEF-0007797	TASI-DEF-0009196		
DTX-197	FDA Orange Book, 2018	2018	TASI-DEF-0009197	TASI-DEF-0010695		
DTX-198	FDA Orange Book, 2019	2019	TASI-DEF-0010696	TASI-DEF-0012256		
DTX-199	FDA Orange Book, 2020	2020	TASI-DEF-0012257	TASI-DEF-0013882		
DTX-200	FDA presentation, "Office of Orphan Products Development: Financial Incentives for CDER Medical Products (accessed 8/12/2020)	8/12/2020	TASI-DEF-0014206	TASI-DEF-0014260		
DTX-201	FDA website, "ANDA 211607," https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=211607 (accessed 6/10/2020)	6/10/2020	TASI-DEF-0003920	TASI-DEF-0003920		
DTX-202	FDA website, "ANDA 211654," https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=211654 (accessed 6/10/2020)	6/10/2020	TASI-DEF-0003921	TASI-DEF-0003921		
DTX-203	FDA website, "Designating an Orphan Product: Drugs and Biological Products," https://www.fda.gov/industry/developing-products-rare-diseases-conditions/designatingorphan-product-drugs-and-biological-products (accessed 3/25/2020)	3/25/2020	TASI-DEF-0014032	TASI-DEF-0014033		
DTX-204	FDA website, "Drugs@FDA Glossary of Terms," 11/14/2017, https://www.fda.gov/drugs/drugapprovals-and-databases/drugsfda-glossaryterms#:~:text=Supplement%20Type&text=To%20change%20a%20label%2C%20market,that%20was%20approved%20by%20FDA	11/14/2017	TASI-DEF-0014261	TASI-DEF-0014264		
DTX-205	FDA website, "Economic Assistance and Incentives for Drug Development," 2/4/2020, https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/economic-assistanceand-incentives-drugdevelopment#:~:text=The%20Orphan%20Drug%20Designation%20Program,for%20approved%20orphan%20drug%20products	2/4/2020	TASI-DEF-0014265	TASI-DEF-0014266		

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Ex. No.	Description	Doc Date	Beginning Bates	Ending Bates	Objections	Admitted
DTX-206	FDA website, "How Can I Better Understand Patents and Exclusivity," 2/1/2016, https://www.fda.gov/industry/fda-basics-industry/how-can-i-better-understand-patents-andexclusivity	2/1/2016	TASI-DEF-0014267	TASI-DEF-0014267		
DTX-207	FDA website, "Search Orphan Drug Designations and Approvals for Hetlioz," https://www.accessdata.fda.gov/scripts/opdlisting/ood/detailedIndex.cfm?cfgridkey=297409 (accessed 3/24/2020)	3/24/2020	TASI-DEF-0014190	TASI-DEF-0014191		
DTX-208	FDA website, Search for: "tasimelteon," https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process (accessed 6/10/2020)	6/10/2020	TASI-DEF-0003922	TASI-DEF-0003923		
DTX-209	FDA, Administrative and Correspondence for NDA 205677, at Reference ID 2899282, 1.1.1	2/2/2011	TASI-DEF-0013883	TASI-DEF-0014031		
DTX-210	FDA, Medical Review for Application Number 205677, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/205677Orig1s000MedR.pdf	2014	TASI-DEF-0014034	TASI-DEF-0014184		
DTX-211	FDA, NDA Approval, 1/31/2014, https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/205677Orig1s000ltr.pdf	1/31/2014	TASI-DEF-0014185	TASI-DEF-0014189		
DTX-212	FDA, Tentative Approval Letter for ANDA 211607, 2/3/2020	2/3/2020	TASI-DEF-0014192	TASI-DEF-0014197		
DTX-213	FDA, Tentative Approval Letter for ANDA 211654, 5/28/2020	5/28/2020	TASI-DEF-0014198	TASI-DEF-0014203		
DTX-214	Formulary Watch, "Drugs in Perspective: Tasimelteon (Hetlioz): Page 3 of 3," 8/6/2014, https://www.formularywatch.com/feature-articles/drugs-perspective-tasimelteonhetlioz/page/0/2	8/6/2014	TASI-DEF-0014275	TASI-DEF-0014277		
DTX-215	FRED, "Japan / U.S. Foreign Exchange Rate" (accessed 7/16/2020)	7/16/2020	TASI-DEF-0020190	TASI-DEF-0020190		
DTX-216	FRED, "U.S. / Euro Foreign Exchange Rate" (accessed 6/18/2020)	6/18/2020	TASI-DEF-0020191	TASI-DEF-0020191		
DTX-217	GoodRx, "Hetlioz," https://www.goodrx.com/hetlioz/medicare-coverage (accessed 6/8/2020)	6/8/2020	TASI-DEF-0014278	TASI-DEF-0014280		
DTX-218	Grabowski, Henry G. (1985), "Issues of Drug Development," Science 228(4702):981	1985	TASI-DEF-0014281	TASI-DEF-0014281		

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Ex. No.	Description	Doc Date	Beginning Bates	Ending Bates	Objections	Admitted
DTX-219	Hetlioz, FDA Label, 10/7/2019	10/7/2019	TASI-DEF-0014332	TASI-DEF-0014342		
DTX-220	Jefferies, "Vanda Pharmaceuticals," 11/15/2013	11/15/2013	TASI-DEF-0002821	TASI-DEF-0002827		
DTX-221	JMP Securities, "Vanda Pharmaceuticals Inc. (VNDA)," 11/15/2013	11/15/2013	TASI-DEF-0002828	TASI-DEF-0002833		
DTX-222	JMP Securities, "Vanda Pharmaceuticals Inc.," 1/17/2013	1/17/2013	TASI-DEF-0002802	TASI-DEF-0002818		
DTX-223	Kaiser Permanente, "Criteria for Drug Coverage: Tasimelteon (Hetlioz)," https://healthy.kaiserpermanente.org/static/health/pdfs/formulary/nw/Hetlioz.pdf (accessed 7/9/2020)	7/9/2020	TASI-DEF-0014389	TASI-DEF-0014389		
DTX-224	Medical News Today, "Insomnia: Everything you need to know," https://www.medicalnewstoday.com/articles/9155 (accessed 3/24/2020)	3/24/2020	TASI-DEF-0014830	TASI-DEF-0014844		
DTX-225	Medical News Today, "What are the best sleeping pills?," 1/23/2020, https://www.medicalnewstoday.com/articles/323775#:~:text=The%20most%20common%20hypnotic%20sleeping,eszopiclone	1/23/2020	TASI-DEF-0014845	TASI-DEF-0014858		
DTX-226	Morningstar, "Vanda Pharmaceuticals Inc VNDA," 2/20/2015	2/20/2015	TASI-DEF-0002843	TASI-DEF-0002847		
DTX-227	PiperJaffray, "Vanda Pharmaceuticals (VNDA)," 11/26/2013	11/26/2013	TASI-DEF-0002834	TASI-DEF-0002840		
DTX-228	Scotchmer, Suzanne (1991), "Standing on the Shoulders of Giants: Cumulative Research and the Patent Law," Journal of Economic Perspectives 5(1):29-41	1991	TASI-DEF-0017716	TASI-DEF-0017730		
DTX-229	Sepracor Inc., Form 10-K, 2005		TASI-DEF-0017731	TASI-DEF-0017781		
DTX-230	Sepracor Inc., Form 10-K, 2008		TASI-DEF-0017782	TASI-DEF-0017939		
DTX-231	Sepracor, Annual Report, 1999	2000	TASI-DEF-0017940	TASI-DEF-0017965		
DTX-232	St. Louis Federal Reserve, Consumer Price Index, https://fred.stlouisfed.org/series/CPIAUCSL (accessed 6/15/2020)	6/15/2020	TASI-DEF-0020192	TASI-DEF-0020192		
DTX-233	Stanford Health Care, "Delayed Sleep Phase Syndrome," https://stanfordhealthcare.org/medical-conditions/sleep/delayed-sleep-phase-syndrome.html (accessed 3/24/2020)	3/24/2020	TASI-DEF-0017974	TASI-DEF-0017976		

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Ex. No.	Description	Doc Date	Beginning Bates	Ending Bates	Objections	Admitted
DTX-234	The New York Times, "COMPANY NEWS; Marion Merrell Plans Deal With Sepracor," 6/3/1993, https://www.nytimes.com/1993/06/03/business/company-news-marion-merrell-plans-deal-with-sepracor.html	6/3/1993	TASI-DEF-0018177	TASI-DEF-0018179		
DTX-235	The Washington Post, "Test of Insomnia Drug Bolsters Vanda's Plan," 11/16/2006	11/16/2006	TASI-DEF-0018180	TASI-DEF-0018182		
DTX-236	Thomson Reuters, Q2 2008 Vanda Pharmaceuticals, Inc. Earnings Conference Call, 8/5/2008	8/5/2008	TASI-DEF-0020123	TASI-DEF-0020129		
DTX-237	Thomson Reuters, Q3 2012 Vanda Pharmaceuticals, Inc. Earnings Conference Call, 11/7/2012	11/7/2012	TASI-DEF-0020130	TASI-DEF-0020139		
DTX-238	Thomson Reuters, Q3 2016 Vanda Pharmaceuticals Inc Earnings Call, 11/2/2016	11/2/2016	TASI-DEF-0020140	TASI-DEF-0020147		
DTX-239	Thomson Reuters, Q4 2012 Vanda Pharmaceuticals, Inc. Earnings Conference Call, 2/12/2013	2/12/2013	TASI-DEF-0020148	TASI-DEF-0020157		
DTX-240	U.S. Bureau of Labor Statistics, Historical Consumer Price Index for all Urban Consumers (CPI-U): U.S. city average, all items, by month - continued, https://www.bls.gov/cpi/tables/supplemental-files/historical-cpi-u-202004.pdf , accessed 6/8/2020	6/8/2020	TASI-DEF-0014343	TASI-DEF-0014346		
DTX-241	UBS, "UBS Large Cap Pharmaceuticals Monthly Handbook," 10/17/2016	10/17/2016	TASI-DEF-0002861	TASI-DEF-0002869		
DTX-242	UBS, "UBS Large Cap Pharmaceuticals Monthly Handbook," 7/23/2012	7/23/2012	TASI-DEF-0002797	TASI-DEF-0002801		
DTX-243	United States Patent and Trademark Office, "General Information Concerning Patents," 10/2015, https://www.uspto.gov/patents-getting-started/general-information-concerningpatents (accessed 6/10/2020)	6/10/2020	TASI-DEF-0018184	TASI-DEF-0018221		
DTX-244	University of Arizona, "Top 200 Pharmaceutical Products by Retail Sales in 2019," https://njardarson.lab.arizona.edu/sites/njardarson.lab.arizona.edu/files/Top%20200%20Drugs%20By%20Retail%20Sales%20in%202019_0.pdf		TASI-DEF-0018183	TASI-DEF-0018183		
DTX-245	Vanda Pharmaceuticals Inc., Form 10-K, 2006		TASI-DEF-0018225	TASI-DEF-0018329		
DTX-246	Vanda Pharmaceuticals Inc., Form 10-K, 2007		TASI-DEF-0018330	TASI-DEF-0018444		

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Ex. No.	Description	Doc Date	Beginning Bates	Ending Bates	Objections	Admitted
DTX-247	Vanda Pharmaceuticals Inc., Form 10-K, 2008		TASI-DEF-0018445	TASI-DEF-0018597		
DTX-248	Vanda Pharmaceuticals Inc., Form 10-K, 2009		TASI-DEF-0018598	TASI-DEF-0018822		
DTX-249	Vanda Pharmaceuticals Inc., Form 10-K, 2010		TASI-DEF-0018823	TASI-DEF-0018933		
DTX-250	Vanda Pharmaceuticals Inc., Form 10-K, 2011		TASI-DEF-0001218	TASI-DEF-0001332		
DTX-251	Vanda Pharmaceuticals Inc., Form 10-K, 2012		TASI-DEF-0019049	TASI-DEF-0019144		
DTX-252	Vanda Pharmaceuticals Inc., Form 10-K, 2013		TASI-DEF-0019145	TASI-DEF-0019246		
DTX-253	Vanda Pharmaceuticals Inc., Form 10-K, 2014		TASI-DEF-0019247	TASI-DEF-0019475		
DTX-254	Vanda Pharmaceuticals Inc., Form 10-K, 2015		TASI-DEF-0019476	TASI-DEF-0019608		
DTX-255	Vanda Pharmaceuticals Inc., Form 10-K, 2016		TASI-DEF-0019609	TASI-DEF-0019751		
DTX-256	Vanda Pharmaceuticals Inc., Form 10-K, 2017		TASI-DEF-0019752	TASI-DEF-0019860		
DTX-257	Vanda Pharmaceuticals Inc., Form 10-K, 2019		TASI-DEF-0019972	TASI-DEF-0020081		
DTX-258	Voet, Martin (2016), The Generic Challenge: Understanding Patents, FDA and Pharmaceutical Life-Cycle Management (Fifth Edition) Boca Raton, FL, Brown Walker Press	2016	TASI-DEF-0020165	TASI-DEF-0020177		
DTX-259	Vanda spreadsheet re Tasimelteon U.S. Forecast May 2012		VNDHTLZ 00022875			
DTX-260	Vanda PowerPoint re Tasimelteon		VNDHTLZ 00221597	VNDHTLZ 00221668		
DTX-261	Vanda PowerPoint re "Managed Care and Trade"		VNDHTLZ 00222078	VNDHTLZ 00222092		
DTX-262	Pricing Q&A		VNDHTLZ 00260524	VNDHTLZ 00260525		
DTX-263	Vanda PowerPoint re "Marketing Overview"	6/10/2014	VNDHTLZ 00381445	VNDHTLZ 00381504		
DTX-264	Vanda PowerPoint re "National Sales Meeting - 09.30.2014 - 10.02.2014"		VNDHTLZ 00385375	VNDHTLZ 00385484		
DTX-265	Vanda PowerPoint re "Board Meeting - March 18-19, 2014"		VNDHTLZ 00391583	VNDHTLZ 00391641		
DTX-266	"2.3.S Drug Substance [Tasimelteon, ██████████.]" from Vanda NDA 205677		VNDHTLZ 01100696	VNDHTLZ 01100724		
DTX-267	"3.2.S.3 Characterization [Tasimelteon, ██████████.]" from Vanda NDA 205677		VNDHTLZ 01101238	VNDHTLZ 01101260		
DTX-268	VEC-162 Circadian Rhythm Sleep Disorders Clinical Development Plan	4/2/2004	VNDHTLZ 01233456	VNDHTLZ 01233508		
DTX-269	Vanda PowerPoint re Pipeline	Jul-04	VNDHTLZ 01234200	VNDHTLZ 01234247		
DTX-270	Vanda PowerPoint re Tasimelteon	12/14/2009	VNDHTLZ 01235181	VNDHTLZ 01235200		
DTX-271	Datamonitor Healthcare Therapy Area Series re "Product Profiles: Insomnia"	Dec-11	VNDHTLZ 01235908	VNDHTLZ 01236039		
DTX-272	Jefferies report re "VNDA - Initiating Coverage"	3/9/2015	VNDHTLZ 01245051	VNDHTLZ 01245084		
DTX-273	Edited Transcript re "VNDA - Q3 2016 Vanda Pharmaceuticals Inc. Earnings Call"	11/2/2016	VNDHTLZ 01246676	VNDHTLZ 01246684		

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Ex. No.	Description	Doc Date	Beginning Bates	Ending Bates	Objections	Admitted
DTX-274	Vanda PowerPoint re "Licensing Opportunity - VEC-162 Melatonin Receptor Agonist"	7/12/2004	VNDHTLZ 01325748	VNDHTLZ 01325776		
DTX-275	Email from Michael Steier re "Hetlioz FDA Approval Coverage, 2/3 - 1pm", attaching "(The Pink Sheet) New Year, New Drugs_Novel Agents with 2014 Action Goals"	2/3/2014	VNDHTLZ 01890470	VNDHTLZ 01890491		
DTX-276	Empire Asset Management Company Investment Thesis	6/10/2014	VNDHTLZ 01891481	VNDHTLZ 01891498		
DTX-277	Vanda 2014 Corporate Presentation		VNDHTLZ 01892954	VNDHTLZ 01892980		
DTX-278	Vanda Clinical Development: VEC-162 "Melatonin Agonist for the Treatment of Circadian Rhythm Sleep Disorders (CRSD)"		VNDHTLZ 02058020	VNDHTLZ 02058029		
DTX-279	Cantor Fitzgerald report re Initiating Coverage	8/22/2018	VNDHTLZ 02169827	VNDHTLZ 02169997		
DTX-280	Vanda PowerPoint re Tasimelteon		VNDHTLZ 02455393	VNDHTLZ 02455411		
DTX-281	Vanda spreadsheet re "Tasi MDD - Vanda P&L"		VNDHTLZ 02475030			
DTX-282	Vanda PowerPoint re "Starting the Cycle of Success"	7/25/2012	VNDHTLZ 02478058	VNDHTLZ 02478163		
DTX-283	Vanda PowerPoint re "Board Meeting - March 15, 2012"		VNDHTLZ 02484554	VNDHTLZ 02484631		
DTX-284	Vanda PowerPoint re "Medical Affairs Valuation"		VNDHTLZ 02550198	VNDHTLZ 02550257		
DTX-285	Hay et al., "Clinical development success rates for investigational drugs," Nature Biotechnology, Vol. 32, 1:40-51	Jan. 2014	VNDHTLZ 02584853	VNDHTLZ 02584865		
DTX-286	Vanda Investor Relations Press Release "Vanda Pharmaceuticals Reports Third Quarter 2010 Results"	11/3/2010	VNDHTLZ 02586909	VNDHTLZ 02586914		
DTX-287	Vanda spreadsheet re "Vanda - Revenue"		VNDHTLZ 02687749			
DTX-288	Korn Ferry International Draft "Confidential Position Specification"	Apr-10	VNDHTLZ 02794350	VNDHTLZ 02794356		
DTX-289	Vanda PowerPoint re "Analyst and Investor Day American Psychiatric Association Annual Meeting"	5/6/2008	VNDHTLZ 02855082	VNDHTLZ 02855149		
DTX-290	Vanda PowerPoint re "VEC-162"	6/20/2006	VNDHTLZ 02906401	VNDHTLZ 02906458		
DTX-291	Vanda PowerPoint re "Board Meeting - September 30, 2015 & October 1, 2015"		VNDHTLZ 02992333	VNDHTLZ 02992461		
DTX-292	Vanda document re "Head of Marketing, Hetlioz" Position Specification		VNDHTLZ 02992507	VNDHTLZ 02992510		
DTX-293	Vanda PowerPoint re "Board Meeting - March 18, 2010"		VNDHTLZ 03039478	VNDHTLZ 03039517		
DTX-294	Circadin® (melatonin) EU Assessment Report ("Circadin® Assessment Report")		TASI-DEF-0002594	TASI-DEF-0002645		
DTX-295	FDA Guidance for Industry, "Food-Effect Bioavailability and Fed Bioequivalence Studies," December 2002 ("FDA Guidance")		TASI-DEF-0002528	TASI-DEF-0002539		

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Ex. No.	Description	Doc Date	Beginning Bates	Ending Bates	Objections	Admitted
DTX-296	Neubauer, D.N., "A review of ramelteon in the treatment of sleep disorders," Neuropsychiatric Disease and Treatment 4(1):69-79 (2008) ("Neubauer")		TASI-DEF-0020206	TASI-DEF-0020216		
DTX-297	Rozerem® (ramelteon) Clinical Pharmacology and Biopharmaceutical Review ("Rozerem® Biopharmaceutical Review")		TASI-DEF-0002646	TASI-DEF-0002761		
DTX-298	Teva Proposed Label		TEVA_TAS-000090492	TEVA_TAS-000090502		
DTX-299	Vanda 2011 10-K					
DTX-300	R.F. Borne et al., "Conformational Analogues of Antihypertensive Agents Related to Guanethidine," 20 J. Med. Chem. 6, 771-76 (1977) ("Borne")	1977	TASI-DEF-0020217	TASI-DEF-0020222		
DTX-301	Chinese Patent Appl. No. CN 102675268, Translation ("CN '268")		TASI-DEF-0020212 TASI-DEF-0020209	TASI-DEF-0020227 TASI-DEF-0020224		
DTX-302	L.F. Fieser and M. Fieser, "Reagents for Organic Synthesis," Vol. 1, 581, John Wiley & Sons (1967)	1967	TASI-DEF-0020339	TASI-DEF-0020362		
DTX-303	A. Rath, "Sodium Bis(methoxyethoxy)aluminium Hydride," 7 Synlett 1140-1141, 1140 (2010) ("Rath")	2010	TASI-DEF-0020337	TASI-DEF-0020338		
DTX-304	T.W.G. Solomons, "Organic Chemistry," 816, John Wiley & Sons (1976)	1976	TASI-DEF-0020363 TASI-DEF-0022267	TASI-DEF-0020367 TASI-DEF-0022307		
DTX-305	Email from Natalie Platt	5/16/2014	VNDHTLZ 02627614			
DTX-306			VNDHTLZ 02627615	VNDHTLZ 02627638		
DTX-307	"	11/27/2006	VNDHTLZ 01096024	VNDHTLZ 01096034		
DTX-308		3/25/2010	VNDHTLZ 01053646	VNDHTLZ 01053648		
DTX-309		3/25/2010	VNDHTLZ 01053641	VNDHTLZ 01053645		
DTX-310	"	3/25/2010	VNDHTLZ 01053640			
DTX-311		11/7/2013	VNDHTLZ 01036193	VNDHTLZ 01036195		
DTX-312		11/7/2013	VNDHTLZ 01036192			
DTX-313		1/3/2012	VNDHTLZ 01006588			
DTX-314		1/3/2012	VNDHTLZ 01006589			
DTX-315		1/3/2012	VNDHTLZ 01006590			
DTX-316	U.S. Patent No. 5,449,683					
DTX-317	McDuff, DeForest, Mickey Ferri, and Noah Brennan (2021), "Patents and Antitrust in the Pharmaceuticals Industry," California Antitrust and Unfair Competition Law 31(2), Forthcoming	2021				

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Ex. No.	Description	Doc Date	Beginning Bates	Ending Bates	Objections	Admitted
DTX-318	McDuff, DeForest, Noah Brennan, and Mickey Ferri (2020), "Thinking Economically about Blocking Patents," Landslide, March/April 2020	2020	TASI-DEF-0022112	TASI-DEF-0022115		
DTX-319	McDuff, DeForest, Ryan Andrews, and Matthew Brundage (2017), "Thinking Economically About Commercial Success," Landslide, March/April 2017	2017	TASI-DEF-0022108	TASI-DEF-0022111		
DTX-320	Vanda Pharmaceuticals Inc., Form 10-K, 2020		TASI-DEF-0022142	TASI-DEF-0022258		
DTX-321	Eastman, "Entraining the free-running circadian clocks of blind people," Lancet, Vol. 386, 1713-1714 (October 31, 2015)					
DTX-322	Advisory Committee Meeting Briefing Materials	11/14/2013	VNDHTLZ 01207629	VNDHTLZ 01207745		
DTX-323	"Responses to Day 120 List of Questions - Clinical"		DRESSMAN 00000117	DRESSMAN 00000165		
DTX-324	Email from Gabrielle Thibodeau to Marlene Dressman et al. re "Updated Scientific Communication Platform Workshop slides"	11/19/2012	VNDHTLZ 00225372			
DTX-325	Vanda PowerPoint re "Scientific Communication Platform Workshop: Core Concepts"		VNDHTLZ 00225373	VNDHTLZ 00225395		
DTX-326	Email from Marlene Dressman to Van Cauter re "Tasimelteon FDA mock Advisory Committee Meeting"	8/28/2013	VNDHTLZ 02021394	VNDHTLZ 02021396		
DTX-327	Email from Curt Wolfgang to Rosa Torres et al. re "Q and A for therapeutic rationale, clinical considerations, and clinpharm"	8/19/2013	VNDHTLZ 00016119			
DTX-328	"Therapeutic Rationale Transcript - Mihael Polymeropoulos"		VNDHTLZ 00016120	VNDHTLZ 00016122		
DTX-329	"Top 10 questions for Clinical Considerations"		VNDHTLZ 00016123	VNDHTLZ 00016127		
DTX-330	"Transcript for Clinical Considerations"		VNDHTLZ 00016128	VNDHTLZ 00016130		
DTX-331	Email from Marlene Dressman to Steven Lockley et al. re "Sleep 2012 Posters For Review"	6/7/2012	VNDHTLZ 00019621	VNDHTLZ 00019624		
DTX-332	Hetlioz® Label	Jan-14	VNDHTLZ 00558265	VNDHTLZ 00558275		
DTX-333	Email from Cathleen Michaloski to Marlene Dressman re "Hetlioz 205677 announcement from the Clinical Pharmacology Division"	2/5/2014	VNDHTLZ 01671307			
DTX-334	"FDA Approval of Hetlioz (Tasimelteon) for the Treatment of Non-24 hour Disorder in Totally Blind Patients"		VNDHTLZ 01671308	VNDHTLZ 01671309		
DTX-335	Email from Marlene Dressman to Louis Licamele re "Hetlioz 205677 announcement from the Clinical Pharmacology Division"	2/5/2014	VNDHTLZ 00231570	VNDHTLZ 00231571		
DTX-336	Email from Gabrielle Thibodeau to Marlene Dressman re "Promotional Messaging Guidebook"	5/19/2015	VNDHTLZ 00237264			

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Ex. No.	Description	Doc Date	Beginning Bates	Ending Bates	Objections	Admitted
DTX-337	Vanda PowerPoint re "Promotional Messaging Guidebook"	8/18/2014	VNDHTLZ 00237265	VNDHTLZ 00237277		
DTX-338	CV of Natalie M. Farris		FARRIS 00000001	FARRIS 00000004		
DTX-339	[REDACTED]	8/22/2011	VNDHTLZ 01002290	VNDHTLZ 01002291		
DTX-340	Vanda F199 VEC-162 Table for discussion					
DTX-341	[REDACTED]		VNDHTLZ 01002293			
DTX-342	[REDACTED]	1/19/2012	VNDHTLZ 01006583	VNDHTLZ 01006585		
DTX-343	[REDACTED]					
DTX-344	[REDACTED]	5/4/2012	VNDHTLZ 02969929			
DTX-345	Batch Record [REDACTED]		VNDHTLZ 02970153	VNDHTLZ 02970188		
DTX-346	Email from Ravi Pandrapragada to Natalie Platt re "32s22-Manufacturing process 0005-Final"	11/20/2014	VNDHTLZ 02641138			
DTX-347	"3.2.S.2 Manufacture [Tasimelteon, [REDACTED]] from Vanda NDA 205677"		VNDHTLZ 02641195	VNDHTLZ 02641250		
DTX-348	Consulting Agreement between Feeney Consulting LLC and Vanda	7/12/2018	FEENEY 00000005	FEENEY 00000007		
DTX-349	Vanda Clinical Study Report "Tasimelteon VP-VEC-162-3203 A Randomized Withdrawal Study to Demonstrate the Maintenance of Effect of 20 mg Tasimelteon in the Treatment of N24HSWD"	4/29/2013	VNDHTLZ 00254220	VNDHTLZ 00254313		
DTX-350	Email from Zehra Tajuddin to Rosa Torres et al. re "1111 Protocol"	1/25/2012	VNDHTLZ 01337265			
DTX-351	Vanda Draft Clinical Study Report "Tasimelteon VP-VEC-162-1111 An Open-Label, Single-Sequence Study in Healthy Subjects to Evaluate the Single-Dose Pharmacokinetics of Tasimelteon Alone and in Combination with a CYP1A2 Inhibitor, Fluvoxamine"		VNDHTLZ 01337266	VNDHTLZ 01337325		
DTX-352	Email from Rosa Torres to Christin Scott et al. re "summaries"	11/12/2009	VNDHTLZ 00239962			
DTX-353	Summaries for latest studies done using melatonin in subjects with non-24 sleep-wake syndrome		VNDHTLZ 00239963	VNDHTLZ 00239964		
DTX-354	"Vanda Pharmaceuticals 2013 Objectives"		VNDHTLZ 00028231	VNDHTLZ 00028232		
DTX-355	Email from Louis Licamele to Billy T. Lee re "Clinicaltrials.gov"	8/26/2010	VNDHTLZ 00945785			

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Ex. No.	Description	Doc Date	Beginning Bates	Ending Bates	Objections	Admitted
DTX-356	"Efficacy and Safety of Tasimelteon Compared With Placebo in Totally Blind Subjects With Non 24-Hour Sleep-Wake Disorder," from ClinicalTrials.gov Protocol Registration System	8/26/20210	VNDHTLZ 00945786	VNDHTLZ 00945789		
DTX-357	Email from Louis Licamele to Shanthakumar Rajaratnam re "Non-24 Questionnaire"	9/13/2012	VNDHTLZ 00946529	VNDHTLZ 00946530		
DTX-358	Email from Louis Licamele to Erica Schreffler re administrative change to Vanda Pharmaceuticals protocol VP-VEC-162-3201	12/7/2012	VNDHTLZ 00947240			
DTX-359	Email from Louis Licamele to Jennifer Hamilton re "03-Clinical_Endpoint-CT-v02"	1/15/2014	VNDHTLZ 00944860			
DTX-360	Vanda PowerPoint re "Clinical Trial Endpoints" by Louis Licamele		VNDHTLZ 00944861	VNDHTLZ 00944896		
DTX-361	Email from Louis Licamele to Mihael H. Polymeropoulos re [REDACTED]: Alaska SLEEP Symposium Slides"	9/15/2016	VNDHTLZ 02183828	VNDHTLZ 02183830		
DTX-362	Vanda PowerPoint re "Hetlioz (tasimelteon), A Novel Treatment for Non-24-Hour Sleep-Wake Disorder: Review of Clinical Evidence" by Louis Licamele	9/16/2016	VNDHTLZ 02183831	VNDHTLZ 02183877		
DTX-363	CV of Ravi K. Pandrapragada		VNDHTLZ 03081562	VNDHTLZ 03081565		
DTX-364	CV of Deepak S. Phadke, Ph.D.		VNDHTLZ 03079208	VNDHTLZ 03079216		
DTX-365	[REDACTED]	9/1/2005	VNDHTLZ 01067790	VNDHTLZ 01067792		
DTX-366	[REDACTED]	9/27/2005	VNDHTLZ 01048341			
DTX-367	Draft report re "Synthesis of VEC-162"		VNDHTLZ 01048342	VNDHTLZ 01048350		
DTX-368	Email from Manish Anand to Manou Ardakani et al. re "FDA input regarding designation of starting materials"	11/13/2007	VNDHTLZ 01053047			
DTX-369	FDA preliminary responses in preparation for Oct. 11, 2007 meeting re "End of Phase 2 (EOP2) Chemistry, Manufacturing and Controls (CMC) Meeting"	9/24/2007	VNDHTLZ 01053048	VNDHTLZ 01053053		
DTX-370	Summary re "Manufacturing Team Meeting - December 9, 2010"		VNDHTLZ 02675501	VNDHTLZ 02675502		
DTX-371	Email from Kristen Boyce to Natalie Platt re "Tasimelteon Drug Substance Summary"	5/17/2011	VNDHTLZ 01103242			
DTX-372	Report re "VEC-162 Drug Substance Manufacturing Process Development"	1/24/2008	VNDHTLZ 01103243	VNDHTLZ 01103253		

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Ex. No.	Description	Doc Date	Beginning Bates	Ending Bates	Objections	Admitted
DTX-373	[REDACTED]	1/12/2005	VNDHTLZ 02681047	VNDHTLZ 02681050		
DTX-374	Singh et al., "Factors Influencing the Application of Literature Methods Towardd the Preparation of a Chiral trans-Cyclopropane Carboxylic Acid Intermediate During Development of a Melatonin Agonist"		VNDHTLZ 02681051	VNDHTLZ 02681079		
DTX-375	Email from John Wetzel to Natalie Platt re "New impurity in the Drug Substance"	3/19/2013	VNDHTLZ 01105601	VNDHTLZ 01105602		
DTX-376	"3.2.S.4 Control of Drug Substance [Tasimelteon, [REDACTED].]" from Vanda NDA 205677		VNDHTLZ 00489570	VNDHTLZ 00489572		
DTX-377	"3.2.S.4 Control of Drug Substance [Tasimelteon, [REDACTED].]" from Vanda NDA 205677		VNDHTLZ 00808239	VNDHTLZ 00808260		
DTX-378	"3.2.S.7 Stability [Tasimelteon, [REDACTED] from Vanda NDA 205677		VNDHTLZ 00446860	VNDHTLZ 00446976		
DTX-379	"2.3.S Drug Substance [Tasimelteon, [REDACTED].]" from Vanda NDA 205677		VNDHTLZ 00255740	VNDHTLZ 00255821		
DTX-380	"3.2.S.7 Stability [Tasimelteon, [REDACTED].]" from Vanda NDA 205677		VNDHTLZ 00808275	VNDHTLZ 00808376		
DTX-381	Vanda Report re "Investigational Medicinal Product: VEC-162/Tasimelteon IND 54776 - Development Safety Update Report #2 - Period covered: 3 March 2011 - 2 March 2012"	5/1/2012	VNDHTLZ 01770778	VNDHTLZ 01770942		
DTX-382	[REDACTED]		VNDHTLZ 02963143	VNDHTLZ 02963144		
DTX-383	Vanda letter and attachments to FDA re "Briefing Book for Type B Meeting for CMC Pre-NDA Meeting"	9/13/2012	VNDHTLZ 00044279	VNDHTLZ 00044369		
DTX-384	Vanda's Supplemental Objections and Responses to Defendants' First Set of Joint Interrogatories to Vanda (Nos. 1-4, 6-8, and 10)	12/17/2019				
DTX-385	[REDACTED]	8/3/2012	VNDHTLZ 00963592	VNDHTLZ 00963595		
DTX-386	Hetlioz® Label	Dec-20				
DTX-387	Vanda Report re "Tasimelteon VP-VEC-162-1107 - An Open-Label, Single Dose, Parallel Group Study to Assess the Effects of Smoking Status, Age and Body Size on the Pharmacokinetics, Safety, and Tolerability of Tasimelteon in Healthy Volunteers"	1/23/2013	VNDHTLZ 00411884	VNDHTLZ 00412236		
DTX-388	Email from Louis Licamele to Mihael H. Polymeropoulos et al. re [REDACTED]	10/18/2013	VNDHTLZ 00016792	VNDHTLZ 00016793		

Defendants' Trial Exhibit List

Ex. No.	Description	Doc Date	Beginning Bates	Ending Bates	Objections	Admitted
DTX-389	Email from Derek Xiao to Louis Licamele et al. re [REDACTED]	10/24/2013	VNDHTLZ 00940815			
DTX-390	Vanda draft "Response to October 17, 2013, Clinical Team Request"		VNDHTLZ 00940816	VNDHTLZ 00940819		
DTX-391	Vanda's Objections and Responses to Defendants' First Set of Joint Interrogatories to Vanda (Nos. 1-10)	7/2/2019				
DTX-392	WO 2015/123389	8/20/2015	VNDHTLZ 00010869	VNDHTLZ 00010903		
DTX-393	Letter from Appleyard Lees IP LLP to European Patent Office re Vanda Pharmaceutical Inc.'s European Patent Application	1/15/2018	SWINTON 00000002	SWINTON 00000013		
DTX-394	"Sleep Disorder (Sedative-Hypnotic) Drug Information" from www.fda.gov					
DTX-395	Email from Steven Lockley to Marlene Dressman et al. re criticisms from New England Journal of Medicine	6/6/2014	VNDHTLZ 01906975	VNDHTLZ 01906979		
DTX-396	Supplement to Lockley et al., Tasimelteon for non-24-hour sleep-wake disorder in totally blind people (SET and RESET): two multicentre, randomised, double-masked, placebo-controlled phase 3 trials, www.thelancet.com (2015)		VNDHTLZ 01643629	VNDHTLZ 01643644		
DTX-397	CV of Jonathan Emens, M.D.	8/27/2021				
DTX-398	CV of David J. Greenblatt, M.D.	12/21/2020				
DTX-399	CV of Deborah A. Jaskot	3/30/2020				
DTX-400	CV of DeForest McDuff, Ph.D.	11/1/2021				
DTX-401	CV of Robert B. Perni, Ph.D.	8/27/2021				
DTX-402	CV of John Weyl Winkelman	2/16/2021				
DTX-403	Barr, David K. (2007), "Patentability of Active Pharmaceutical Ingredients," from PLI's Course Handbook Developments in Pharmaceutical and Biotech Patent Law #17180, adapted from Chapter 7 of PLI's Pharmaceutical and Biotech Patent Law, http://www.pli.edu/emktg/toolbox/patpharm_ing36.doc	2007	TASI-DEF-0003094	TASI-DEF-0003145		
DTX-404	e-CFR, Electronic Code of Federal Regulations, §316.20	8/4/2020	TASI-DEF-0003661	TASI-DEF-0003670		
DTX-405	Grabowski, Henry, et al. (2012), "Does Generic Entry Always Increase Welfare?," Food and Drug Law Journal 67(3):373-391	2012	TASI-DEF-0014312	TASI-DEF-0014331		
DTX-406	Mayo Clinic, "Jet lag disorder," https://www.mayoclinic.org/diseases-conditions/jetlag/symptoms-causes/syc-20374027 (accessed 3/24/2020)	3/24/2020	TASI-DEF-0014822	TASI-DEF-0014829		

Defendants' Trial Exhibit List

Ex. No.	Description	Doc Date	Beginning Bates	Ending Bates	Objections	Admitted
DTX-407	Murray, Fiona et al. (2016), "Of Mice and Academics: Examining the Effect of Openness on Innovation," American Economic Journal: Economic Policy 8(1):212-252	2016	TASI-DEF-0014859	TASI-DEF-0014900		
DTX-408	National Organization for Rare Disorders, "Smith Magenis Syndrome," https://rarediseases.org/rare-diseases/smith-magenis-syndrome/ (accessed 3/24/2020)	3/24/2020	TASI-DEF-0015070	TASI-DEF-0015074		
DTX-409	Robbins, Richard L. (1963), "Subtests of 'Nonobviousness': A Nontechnical Approach to Patent Validity," University of Pennsylvania Law Review Vol.112:1169-1184	1963	TASI-DEF-0022118	TASI-DEF-0022133		
DTX-410	Declaration regarding publication of Clinical Trials					
DTX-411	Chinese Patent Appl. No. CN 103087019, Translation		TASI-DEF-0000991 TASI-DEF_TRANSLATION0000582	TASI-DEF-0001005 TASI-DEF_TRANSLATION0000588		
DTX-412	Attachment B-1 to the Expert Report of DeForest McDuff, Ph.D. - Hetlioz FDA Orange Book Patents	8/14/2020				
DTX-413	Attachment B-2 to the Expert Report of DeForest McDuff, Ph.D. - Hetlioz Sought Indications	8/14/2020				
DTX-414	Attachment D-1 to the Expert Report of DeForest McDuff, Ph.D. - Hetlioz NPV: All R&D (based on Grabowski Ex. 5)	8/14/2020				
DTX-415	Attachment D-5 to the Expert Report of DeForest McDuff, Ph.D. - Hetlioz NPV: Risk-Adjusted (Probability of Phase Transitions)	8/14/2020				
DTX-416	Attachment B-1 (Updated) to the Supplemental Expert Report of DeForest McDuff, Ph.D. - Hetlioz FDA Orange Book Patents	11/1/2021				
DTX-417	Attachment D-1 (Updated) to the Supplemental Expert Report of DeForest McDuff, Ph.D. - Hetlioz NPV: All R&D (based on Third Grabowski Report, Ex. D)	11/1/2021				
DTX-418	Attachment D-5 (Updated) to the Supplemental Expert Report of DeForest McDuff, Ph.D. - Hetlioz NPV: Risk-Adjusted (Probability of Phase Transitions)	11/1/2021				

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

VANDA PHARMACEUTICALS
INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA,
INC., et al.,

Defendants.

C.A. No. 18-651-CFC
(Consolidated)

Exhibit 12 – Joint Trial Exhibit List

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

C.A. No. 18-00651-CFC

Vanda Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc., et al.

Joint Trial Exhibit List

<u>Exhibit Number</u>	<u>Date</u>	<u>Description</u>	<u>Beginning Bates Number</u>	<u>Ending Bates Number</u>	<u>Admitted</u>
1	4/17/2018	U.S. Patent No. RE46,604	VNDHTLZ 00000001	VNDHTLZ 00000042	
2	8/13/2019	U.S. Patent No. 10,376,487	VNDHTLZ 03092221	VNDHTLZ 03092224	
3	10/22/2019	U.S. Patent No. 10,449,176	VNDHTLZ 03093930	VNDHTLZ 03093965	
4	4/7/2020	U.S. Patent No. 10,610,511	VNDHTLZ 03102604	VNDHTLZ 03102608	
5	12/11/2018	U.S. Patent No. 10,149,829	VNDHTLZ 02592595	VNDHTLZ 02592629	
6	8/15/2017	U.S. Patent No. 9,730,910	VNDHTLZ 00000159	VNDHTLZ 00000199	

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<u>Exhibit Number</u>	<u>Date</u>	<u>Description</u>	<u>Beginning Bates Number</u>	<u>Ending Bates Number</u>	<u>Admitted</u>
7	6/23/2015	U.S. Patent No. 9,060,995	VNDHTLZ 00000043	VNDHTLZ 00000076	
8	1/10/2017	U.S. Patent No. 9,539,234	VNDHTLZ 00000077	VNDHTLZ 00000117	
9	1/24/2017	U.S. Patent No. 9,549,913	VNDHTLZ 00000118	VNDHTLZ 00000158	
10	1/2/2018	U.S. Patent No. 9,855,241	VNDHTLZ 00000200	VNDHTLZ 00000235	
11	9/10/2018	U.S. Patent No. 5,856,529	TASI-DEF-0000808	TASI-DEF-0000832	
12	2/24/2016	File History of U.S. Patent No. RE46604	VNDHTLZ 00000270	VNDHTLZ 00001053	
13	6/11/2014	File History of U.S. Patent No. 9,060,995	VNDHTLZ 00001054	VNDHTLZ 00002103	
14	4/16/2015	File History of U.S. Patent No. 9,539,234	VNDHTLZ 00002104	VNDHTLZ 00002760	
15	7/24/2014	File History of U.S. Patent No. 9,549,913	VNDHTLZ 00002761	VNDHTLZ 00004916	
16	10/9/2014	File History of U.S. Patent No. 9,730,910	VNDHTLZ 00004917	VNDHTLZ 00006384	
17	12/14/2016	File History of U.S. Patent No. 9,855,241	VNDHTLZ 00006385	VNDHTLZ 00006763	
18	2/25/2020	File History of U.S. Patent No. 10,071,977	VNDHTLZ 00010621	VNDHTLZ 00011040	
19	12/16/2016	File History of U.S. Patent No. 10,149,829	VNDHTLZ 00011225	VNDHTLZ 00011659	
20	10/10/2014	File History of U.S. Patent No. 10,376,487	VNDHTLZ 03090202	VNDHTLZ 03091167	
21	11/26/2017	File History of U.S. Patent No. 10,449,176	VNDHTLZ 03091168	VNDHTLZ 03091750	
22	7/19/2019	File History of U.S. Patent No. 10,610,511	VNDHTLZ 03100520	VNDHTLZ 03100643	
23		File History of U.S. Patent No. 8,785,492	VNDHTLZ 00006764	VNDHTLZ 00007436	

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<u>Exhibit Number</u>	<u>Date</u>	<u>Description</u>	<u>Beginning Bates Number</u>	<u>Ending Bates Number</u>	<u>Admitted</u>
24	1/26/2012	Provisional Application 61/590,974	VNDHTLZ 00007437	VNDHTLZ 00007464	
25	10/2019	HETLIOZ (tasimelteon) capsules 20 mg, Label	VNDHTLZ 03081676	VNDHTLZ 03081686	
26	12/2020	Hetlioz (Tasimelteon) Capsules 20 Mg, Label	VNDHTLZ 03095123	VNDHTLZ 03095144	
27	7/24/2018	Tasimelteon Capsules 20 MG Label	TEVA_TAS-000018765	TEVA_TAS-000018774	
28	12/1/2020	Tasimelteon Capsules 20 MG Label	TEVA_TAS-000090482	TEVA_TAS-000090491	

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C.A. No. 18-00651-CFC

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<u>Exhibit Number</u>	<u>Date</u>	<u>Description</u>	<u>Beginning Bates Number</u>	<u>Ending Bates Number</u>	<u>Admitted</u>
29	10/1/2019	Tasimelteon Capsule 20MG Label	APO-TASI-0131331	APO-TASI-0131341	
30	4/1/2019	Tasimelteon Capsule 20MG Label	APO-TASI-0129448	APO-TASI-0129458	
31	2/1/2021	Tasimelteon Capsule 20MG Label	APO-TASI-0131610	APO-TASI-0131621	
32	10/1/2019	3 Way Labeling Comparison Prescribing Information	APO-TASI-0131352	APO-TASI-0131368	
33	7/22/2005	Rozerem® Label (Including Revisions Thereto)	TASI-DEF-0001767	TASI-DEF-0001790	
34	1/2018	Manufacture, Tasimelteon Capsules	APO-TASI-0001466	APO-TASI-0001470	
35	1/2018	Manufacture, Tasimelteon Capsules	APO-TASI-0001497	APO-TASI-0001498	
36	1/2018	Manufacture, Tasimelteon, Apotex Pharmachem Inc.	APO-TASI-0002429	APO-TASI-0002429	
37	1/30/2018	Patent Certification Statement: Paragraph IV Certification - Abbreviated New Drug Application for Tasimelteon Capsules, 20 mg	APO-TASI-0000402	APO-TASI-0000403	

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<u>Exhibit Number</u>	<u>Date</u>	<u>Description</u>	<u>Beginning Bates Number</u>	<u>Ending Bates Number</u>	<u>Admitted</u>
38	11/15/2018	Patent Certification Statement: Paragraph IV Certification - Abbreviated New Drug Application for Tasimelteon Capsules, 20 mg	APO-TASI-0129294	APO-TASI-0129294	
39	2/27/2019	Patent Certification Statement: Paragraph IV Certification - Abbreviated New Drug Application for Tasimelteon Capsules, 20 mg	APO-TASI-0129397	APO-TASI-0129397	
40	11/21/2019	Patent Certification Statement: Paragraph IV Certification - Abbreviated New Drug Application for Tasimelteon Capsules, 20 mg	APO-TASI-0131388	APO-TASI-0131388	
41	12/6/2019	Patent Certification Statement: Paragraph IV Certification - Abbreviated New Drug Application for Tasimelteon Capsules, 20 mg	APO-TASI-0131422	APO-TASI-0131422	
42	5/16/2017	Apotex Drug Master File on Tasimelteon	APO-TASI-0006719	APO-TASI-0008492	
43		Summary Of Product Characteristics, Circadin	TASI-DEF-0002568	TASI-DEF-0002593	
44	4/10/2017	Specification and Certificate of Analysis	APO-TASI-0111964	APO-TASI-0111967	
45	1/31/2018	Tasimelteon Capsules - Control of Drug Product	APO-TASI-0000952	APO-TASI-0000955	
46	8/8/2018	Specification and Certificate of Analysis - Tasimelteon Capsules 20MG	APO-TASI-0129596	APO-TASI-0129598	

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<u>Exhibit Number</u>	<u>Date</u>	<u>Description</u>	<u>Beginning Bates Number</u>	<u>Ending Bates Number</u>	<u>Admitted</u>
47	1/31/2018	Tasimelteon, Justification of Specification	APO-TASI-0001777	APO-TASI-0001784	
48	1/31/2018	3.2.S .2.2 Description of Manufacturing Process and Process Controls	APO-TASI-0002432	APO-TASI-0002434	
49	1/31/2018	Apotex Report: Validation of Test Method TASI-IMP-20-SG Issue #1 for Degradation Products of Tasimelteon Capsules 20 mg	APO-TASI-0000969	APO-TASI-0001144	
50	11/2017	Pharmaceutical Development Report Tasimelteon Capsules 20 mg	APO-TASI-0001538	APO-TASI-0001626	
51	1/31/2018	Report: Validation of Test Method Tasi-Ds-22-Sg Issue #1 for Related Compounds of Tasimelteon Drug Substance	APO-TASI-0002141	APO-TASI-0002307	
52	10/20/2017	Clinical Study Report - TASI-IMCP-05SB01-2FA	APO-TASI-0003218	APO-TASI-0003301	
53	11/7/2012	Clinical Trials: Study NCT01163032	VNDHTLZ 00027626	VNDHTLZ 00027630	
54	6/3/2009	Clinical Study Report for VP-VEC-162-1104, Vanda Pharmaceuticals Inc.	VNDHTLZ 00104112	VNDHTLZ 00104115	
55	5/18/2009	Report for Vanda Protocol No. VP-VEC-162-1101 [REDACTED]	VNDHTLZ 00107334	VNDHTLZ 00107639	
56	12/17/2007	Clinical Study Report for VP-VEC-162-1102, Vanda Pharmaceuticals Inc.	VNDHTLZ 00403884	VNDHTLZ 00404033	

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<u>Exhibit Number</u>	<u>Date</u>	<u>Description</u>	<u>Beginning Bates Number</u>	<u>Ending Bates Number</u>	<u>Admitted</u>
57	4/24/2013	Clinical Study Report Addendum- VP-VEC-162-1103 - A Double-Blind Randomized Cross-Over Trial to Define the ECG Effects of VEC-162 Using a Clinical and a Supratherapeutic Dose Compared to Placebo and Moxifloxacin (A Positive Control) in Healthy Men and Women: A Thorough ECG Trial	VNDHTLZ 00422161	VNDHTLZ 00422811	
58	4/29/2013	Clinical Study Report - Tasimelteon VP-VEC-162-3201- A Multicenter, Randomized, Double-Mask, Placebo-Controlled, Parallel Study to Investigate the Efficacy and Safety of 20 MG Tasimelteon Versus Placebo in Totally Blind Subjects with N24HSWD Followed by and Ole Phase	VNDHTLZ 00425137	VNDHTLZ 00426247	
59	4/29/2013	Vanda Clinical Study Report "Tasimelteon VP-VEC-162-3203 A Randomized Withdrawal Study to Demonstrate the Maintenance of Effect of 20 mg Tasimelteon in the Treatment of N24HSWD"	VNDHTLZ 00254220	VNDHTLZ 00254313	
60	10/2/2000	Report for Protocol No. CN116-003	VNDHTLZ 01295579	VNDHTLZ 01295582	
61	2/16/1999	Report for Protocol No. CN116-001	VNDHTLZ 01319894	VNDHTLZ 01320002	
62	12/14/1999	Report for Protocol No. CN116-004	VNDHTLZ 01320586	VNDHTLZ 01320709	
63	11/19/2009	Letter From J. Feeney To Dr. Cote Re: Vec-162/Tasimelteon Non-24 Hour Sleep-Wake Disorder In Blind Individuals Without Light Perception Request For Orphan Drug Designation	VNDHTLZ 01199450	VNDHTLZ 01199481	
64	1/6/2011	Letter from R. Katz to G. Birznieks re: Investigational New Drug Application (IND)	VNDHTLZ 00393053	VNDHTLZ 00393062	
65	11/28/2012	Letter from R. Katz to M. Dressman re Advice/Information Request	VNDHTLZ 00013093	VNDHTLZ 00013095	

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<u>Exhibit Number</u>	<u>Date</u>	<u>Description</u>	<u>Beginning Bates Number</u>	<u>Ending Bates Number</u>	<u>Admitted</u>
66	10/13/2011	Letter from M. Dressman to R. Katz re IND 54, 776 — Serial No. 138 VEC462/tasimelteon General Correspondence: Briefing Book for Type A Meeting for VP-VEC- / 62-3203	VNDHTLZ 02683478	VNDHTLZ 02683539	
67	6/8/2012	Letter from R. Katz to M. Dressman re Advice/Information Request	VNDHTLZ 01924705	VNDHTLZ 01924707	
68	8/16/2013	Letter From A. Crerar To P. Teitell Re Pre Approval Inspection For Tasimelteon (Vec-162)	VNDHTLZ 01160824	VNDHTLZ 01160839	
69	8/10/2017	Letter from L. Brownell to FDA re: Amendment, eCTD, Type II Drug Master File No. 031843	APO-TASI-0008790	APO-TASI-0009152	
70	4/2/2018	Letter from K. Krishnan to Vanda Pharmaceuticals, Inc. re: Apotex proprietary information regarding its proposed Tasimelteon Product			
71	2/27/2019	Letter from K. Krishnan to Vanda Pharmaceuticals, Inc. re Tasimelteon, 20mg: Notification of Certification of Noninfringement, Invalidity and/or Unenforcability of US Patent No. 10,149,829 pursuant to 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act			
72	11/15/2018	Letter from K. Krishnan to Vanda Pharmaceuticals, Inc. re: Apotex's proprietary information concerning its proposed Tasimelteon oral capsule product.			
73	4/5/2014	[REDACTED]	APO-TASI-0010895	APO-TASI-0010927	
74	3/1/2018	[REDACTED]	APO-TASI-0025291	APO-TASI-0025305	

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C.A. No. 18-00651-CFC

Vanda Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc., et al.

<u>Exhibit Number</u>	<u>Date</u>	<u>Description</u>	<u>Beginning Bates Number</u>	<u>Ending Bates Number</u>	<u>Admitted</u>
75	2/11/2016	[REDACTED]	APO-TASI-0027425	APO-TASI-0027441	
76	2/5/2018	[REDACTED]	APO-TASI-0028597	APO-TASI-0028676	
77	6/13/2017	[REDACTED]	APO-TASI-0101398	APO-TASI-0101415	
78	4/6/2015	[REDACTED]	APO-TASI-0120463	APO-TASI-0120548	
79	4/7/2006	Email from M. Anand to C. Douglas re VEC-162 Proposal	VNDHTLZ 01164602	VNDHTLZ 01164611	
80	10/23/2015	[REDACTED]	APO-TASI-0116235	APO-TASI-0116256	
81	9/14/2016	[REDACTED]	APO-TASI-0130137	APO-TASI-0130729	
82	1/23/2014	Center For Drug Evaluation And Research, Application Number 205677Orig1S000, Summary Review	VNDHTLZ 00031466	VNDHTLZ 00031476	
83	1/23/2014	Center for Drug Evaluation and Research, Application Number 205677Orig1S000, Summary Review	VNDHTLZ 00999355	VNDHTLZ 00999365	
84	1/31/2014	Center for Drug Evaluation and Research, Application Number 205677Orig1S000, Office Director Memo	VNDHTLZ 00819675	VNDHTLZ 00819684	
85	7/30/2013	Medical Review Application Number 205677Origis000	VNDHTLZ 01671784	VNDHTLZ 01671934	
86	7/17/2017	[REDACTED]	APO-TASI-0098694	APO-TASI-0098819	

FOR THE DISTRICT OF DELAWARE

C.A. No. 18-00651-CFC

Vanda Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc., et al.

<u>Exhibit Number</u>	<u>Date</u>	<u>Description</u>	<u>Beginning Bates Number</u>	<u>Ending Bates Number</u>	<u>Admitted</u>
87	1/2000	Hartter I, S., et al. <i>Increased Bioavailability Of Oral Melatonin After Fluvoxamine Coadministration</i> , Clinical Pharmacology & Therapeutics, Vo. 67 No. 1, January 2000	TASI-DEF-0000011	TASI-DEF-0000016	
88	4/2001	Hartter, Differential Effects Of Fluvoxamine And Other Antidepressants On The Biotransformation Of Melatonin, Journal Of Clinical Psychopharmacology, Vol. 21 No. 2	TASI-DEF-0000091	TASI-DEF-0000098	
89	11/21/2002	Vacharajani, Preclinical Pharmacokinetics And Metabolism Of Bms-214,778, A Novel Melatonin Receptor Agonist, Journal Of Pharmaceutical Sciences, Vol. 92, No. 4, April 2003	TASI-DEF-0000017	TASI-DEF-0000029	
90	5/17/2010	Obach, <i>Metabolism Of Ramelteon In Human Liver Microsomes And Correlation With The Effect Of Fluvoxamine On Ramelteon Pharmacokinetics</i> , The American Society For Pharmacology And Experimental Therapeutics Vol. 38 No. 8	TASI-DEF-0000099	TASI-DEF-0000109	
91	2011	Pandi-Perumal, <i>Pharmacotherapy Of Insomnia With Ramelteon: Safety, Efficacy And Clinical Applications</i> , Journal Of Central Nervous System Disease 2011:3 51-65	TASI-DEF-0000192	TASI-DEF-0000206	
92	2010	Ferguson, S., et al. <i>Melatonin agonists and insomnia</i> , Expert Rev. Neurother, 2010	TASI-DEF-0000219	TASI-DEF-0000232	
93	8/1/2007	Lynch and Price, <i>The Effect of Cytochrome P450 Metabolism on Drug Response, Interactions, and Adverse Effects</i> , AAFP Volume 76 Number 3	TASI-DEF-0000673	TASI-DEF-0000678	

FOR THE DISTRICT OF DELAWARE

C.A. No. 18-00651-CFC

Vanda Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc., et al.

<u>Exhibit Number</u>	<u>Date</u>	<u>Description</u>	<u>Beginning Bates Number</u>	<u>Ending Bates Number</u>	<u>Admitted</u>
94	1/2010	Greenblatt and Moltke, <i>Clinical Studies of Drug-Drug Interactions: Design and Interpretation</i> , In Enzyme and Transporter Based Drug-Drug Interactions: Progress and Future Challenges, Springer	TASI-DEF-0001634	TASI-DEF-0001658	
95	2011	Greenblatt, <i>Introduction to Drug-Drug Interactions</i> , Infectious Disease, Springer	TASI-DEF-0001659	TASI-DEF-0001669	
96	2017	Greenblatt, <i>Mechanisms and Consequences of Drug-Drug Interactions</i> , Clinical Pharmacology in Drug Development 2017,6(2)	TASI-DEF-0001670	TASI-DEF-0001676	
97	8/13/2014	HETLIOZ Solutions™ & Case Management – FIELD USE	VNDHTLZ 00381962	VNDHTLZ 00381968	
98	9/30/2013	Tasimelteon Commercial Launch Plan, Vanda Pharmaceuticals Inc.	VNDHTLZ 00961821	VNDHTLZ 00961925	
99	2/26/2004	License, Development and Commercialization Agreement by and between BMS and Vanda	VNDHTLZ 00977439	VNDHTLZ 00977495	
100	8/15/2004	Amended and Restated License Development and Commercialization Agreement by and between Bristol-Myers Squibb Company and Vanda Pharmaceuticals	VNDHTLZ 00977276	VNDHTLZ 00977328	
101	2/26/2004	License, Development and Commercialization Agreement between Vanda Pharmaceuticals Inc. and Bristol-Myers Squibb Company	VNDHTLZ 00977382	VNDHTLZ 00977438	
102	4/1997	Preclinical Lead Profile, Sleep/Melatonin Program BMS-214778, CNS Drug Discovery	VNDHTLZ 01191756	VNDHTLZ 01191791	
103	5/21/2012	Torres and Schreffler, <i>Tasimelteon Amendment No. 9/U.S.to VP-VEC-162-3201 A Multicenter, Randomized, Double-Mask, Placebo-Controlled, Parallel Study to Investigate the Efficacy and Safety of 20 MG Tasimelteon Versus Placebo in Totally Blind Subjects with N24HSWD Followed by an Ole Phase</i>	VNDHTLZ 01203613	VNDHTLZ 01203711	

FOR THE DISTRICT OF DELAWARE

C.A. No. 18-00651-CFC

Vanda Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc., et al.

<u>Exhibit Number</u>	<u>Date</u>	<u>Description</u>	<u>Beginning Bates Number</u>	<u>Ending Bates Number</u>	<u>Admitted</u>
104	11/14/2013	Vanda Tasimelteon Advisory Committee Meeting Briefing Materials	VNDHTLZ 01207629	VNDHTLZ 01207745	
105	6/23/2017	Conceptual economic model for HETLIOZ® (Tasimelteon) with HTA feasibility assessment using this conceptual model, Tolley Health Economics	VNDHTLZ 01210112	VNDHTLZ 01210173	
106	5/5/2015	HETLIOZ® Brand Update	VNDHTLZ 01234846	VNDHTLZ 01234978	
107	4/17/2008	Tasimelteon Business Plan – Commercial Evaluation Drafts, Vanda Pharmaceuticals Inc.	VNDHTLZ 01352648	VNDHTLZ 01352780	
108	10/18/2013	Peripheral and Central Nervous System (PCNS) Drugs Advisory Committee - Tasimelteon (melatonin agonist)	VNDHTLZ 01670659	VNDHTLZ 01670861	
109	2/13/2004	Assessment of BMS-214778 for in-licensing	VNDHTLZ 01724630	VNDHTLZ 01724644	
110	10/10/2003	Vanda Pharmaceuticals Presentation, BMS-214778, Presented to NDA Partners	VNDHTLZ 01756838	VNDHTLZ 01756879	
111	12/9/2003	Polymeropoulos Presentation on BMS-214778 Melatonin Agonist for the Treatment of Circadian Rhythm Disorders	VNDHTLZ 01757522	VNDHTLZ 01757561	
112	6/25/2014	Educational Grant Request Proposal – Non-24 Hour Sleep-Wake Disorder: Assessing the Evolving Approaches to Diagnosis and Treatment, Vanda Pharmaceuticals Inc.	VNDHTLZ 01891980	VNDHTLZ 01892006	
113	8/18/2014	Promotional Messaging Guidebook, Hetlio, Presentation	VNDHTLZ 01946510	VNDHTLZ 01946522	

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C.A. No. 18-00651-CFC

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114	12/14/1999	Clinical Study Report - BMS-274778 - A Placebo-Controlled, Double-Blind Study of Three Fixed Doses of BMS-214778 in the Treatment of Elderly Patients with Insomnia	VNDHTLZ 02059698	VNDHTLZ 02059821	
115	4/9/2013	IND #54,776 Submission No. 004 – Chemistry, Manufacturing and Controls	VNDHTLZ 02077830	VNDHTLZ 02077906	
116	7/10/2001	Lewy et al., <i>Capturing the circadian rhythms of free-running blind people with 0.5 mg melatonin</i> , Brain Research 918 (2001)	VNDHTLZ 02213579	VNDHTLZ 02213583	
117	2/18/2014	Align24 Non-24 Training Program Non-24 Market Dynamics, Vanda Pharmaceuticals Inc.	VNDHTLZ 02223242	VNDHTLZ 02223283	
118	2/27/2004	[REDACTED]	VNDHTLZ 02456066	VNDHTLZ 02456082	
119	3/11/2014	Hetlitz Visual Aid Testing, Vanda Pharmaceuticals Inc.	VNDHTLZ 02479718	VNDHTLZ 02479760	
120	4/4/2016	Hetlitz® And Non-24 Circadian Sleep-Wake Disorder Onboarding Training Guide, Vanda Pharmaceuticals Inc	VNDHTLZ 02554034	VNDHTLZ 02554045	
121	2002	Lewy et al. Low, But Not High, Doses Of Melatonin Entrained A Free-Running Blind Person With A Long Circadian Period, Chronobiology International, 19(3), 649-658 (2002)	VNDHTLZ 02587615	VNDHTLZ 02587626	

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122	6/19/2003		VNDHTLZ 02779170	VNDHTLZ 02779188	
123	3/21/2004	Vanda Pharmaceuticals Inc. Financing Presentation March 2004	VNDHTLZ 02816641	VNDHTLZ 02816693	
124	5/18/2010	Zee et al. <i>Effects Of Ramelteon On Insomnia Symptoms Induced By Rapid Eastward Travel</i> , Sleep Medicine 11: (2010) 525-533	VNDHTLZ 03009651	VNDHTLZ 03009659	
125	7/2010	Burgess et al. <i>Human Phase Response Curves to Three Days of Daily Melatonin: .5mg Versus 3.0 m</i> , (J Clin Endocrinol Metab 95: 3325-3331, 2010)	VNDHTLZ 03064037	VNDHTLZ 03064043	
126	2/19/2019	Vanda Pharmaceuticals Inc. Form 10-K	VNDHTLZ 03080244	VNDHTLZ 03080354	
127	2008	Burgess, H., et al., <i>A three pulse phase response curve to three milligrams of melatonin in humans</i> , J Physiol 586.2 (2008)	VNDHTLZ 03083160	VNDHTLZ 03083169	
128	2/2012	FDA, Guidance for the Industry - Drug Interaction Studies —Study Design, Data Analysis, Implications for Dosing, and Labeling Recommendation	VNDHTLZ 03083706	VNDHTLZ 03083784	
129	2006	Ogilvie et al. <i>Accelerated Communication Glucuronidation Converts Gemfibrozil to a Potent, Metabolism-Dependent Inhibitor of CYP2C8: Implications for Drug-Drug Interactions</i> , Drug Metabolism and Disposition	VNDHTLZ 03084052	VNDHTLZ 03084058	
130	1996	Pearce, <i>Identification Of The Human P450 Enzymes Involved In Lansoprazole Metabolism</i> , 277 Pharmacology And Experimental Therapeutics 805	VNDHTLZ 03084279	VNDHTLZ 03084290	

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131	4/2012	DiMasi, J. and H. Grabowski, R&D Costs and Returns to New Drug Development: A Review of the Evidence, The Oxford Handbook of the Economics of the Biopharmaceutical Industry, 2012, P. Danzon and S. Nicholson (Eds.), New York, NY: Oxford University Press, pp. 24–28	VNDHTLZ 03084547	VNDHTLZ 03084573	
132	2016	DiMasi, J. et al., <i>Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs</i> , Journal of Health Economics, 47, pp. 20–33,	VNDHTLZ 03084574	VNDHTLZ 03084587	
133	2002	Grabowski, H. et al., Returns on Research and Development for 1990s New Drug Introductions, Pharmacoeconomics, 20(3), pp. 11–29	VNDHTLZ 03084626	VNDHTLZ 03084644	
134	6/2008	Grabowski, H., Follow-on Biologics: Data Exclusivity and the Balance Between Innovation and Competition, Nature Reviews: Drug Discovery, 7(6), pp. 479–488	VNDHTLZ 03084645	VNDHTLZ 03084654	
135	10/2018	Orphan Drugs in the United States Growth Trends in Rare Disease Treatments, IQVIA Institute for Human Data Science, October 2018,	VNDHTLZ 03086980	VNDHTLZ 03087013	
136	12/2006	Neuvonen et al. Drug Interactions With Lipid-Lowering Drugs: Mechanisms And Clinical Relevance, 80 Clinical Pharmacology And Therapeutics 565	VNDHTLZ 03089573	VNDHTLZ 03089589	
137	4/11/1995	Deacon And Arendt, Melatonin-Induced Temperature Suppression And Its Acute Phase-Shifting Effects Correlate In A Dose-Dependent Manner In Humans, 688 Brain Research 77 (1995)	VNDHTLZ 03089875	VNDHTLZ 03089883	

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138	10/12/2000	Arendt, Melatonin, Circadian Rhythms, And Sleep, 343 New England J. Med. 1114, 1115 (2000)	VNDHTLZ 03089940	VNDHTLZ 03089944	
139	2006	Yaron Dagan et al. Advanced, Delayed, Irregular, And Free-Running Sleep—Wake Disorders, In Sleep: A Comprehensive Handbook, 385 (Lee-Chiong, T., Ed. 2006).	VNDHTLZ 03090014	VNDHTLZ 03090020	
140	2011	Kathryn Reid & Phyllis Zee, Circadian Disorders Of The Sleep–Wake Cycle, In Principles And Practice Of Sleep Medicine 477 (5Th Ed. 2011)	VNDHTLZ 03090021	VNDHTLZ 03090033	
141		Management Association	VNDHTLZ 03096350	VNDHTLZ 03096352	
142	1/31/2018	Quality Overall Summary	APO-TASI-0000067	APO-TASI-0000176	
143	12/1/2015	Emens et al. <i>Effect of Light and Melatonin and Other Melatonin Receptor Agonists on Human Circadian Physiology</i> , Sleep Med Clin. 2015 December; 10(4): 435-453	VNDHTLZ 03083463	VNDHTLZ 03083489	
144	10/2003	Hack et al. The Effects Of Low-Dose 0.5-Mg Melatonin On The Free-Running Circadian Rhythms Of Blind Subjects, Journal Of Biological Rhythms, Vol. 18 No. 5, October 2003	TASI-DEF-0000233	TASI-DEF-0000242	
145	2000	Lockley et al. Melatonin Administration Can Entrain The Free-Running Circadian System Of Blind Subjects, 164 Journal Of Endocrinology R1 (2000)	TASI-DEF-0001923	TASI-DEF-0001928	

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146	10/12/2000	Sack et al. Entrainment Of Free-Running Circadian Rhythms By Melatonin In Blind People, 343 The New England Journal Of Medicine 1070 (2000)	TASI-DEF-0001929	TASI-DEF-0001936	
147	2015	Auger et al. <i>Clinical Practice Guideline For The Treatment Of Intrinsic Circadian Rhythm Sleep-Wake Disorder: Advanced Sleep-Wake Phase Disorder (Aswpd), Delayed Sleep-Wake Phase Disorder (Dswpd), Non-24-Hour Sleep-Wake Rhythm Disorder (N24Swd), And Irregular Sleep-Wake Rhythm Disorder (ISWRD) An Update For 2015</i> , 11 Journal Of Clinical Sleep Medicine 1199-236	VNDHTLZ 01243168	VNDHTLZ 01243205	
148	2015	Ogilvie et al. <i>Clinical Assessment Of Drug-Drug Interactions Of Tasimelteon, A Novel Dual Melatonin Receptor Agonist</i> , 55 The Journal of Clinical Pharmacology 1004	VNDHTLZ 02118929	VNDHTLZ 02118936	
149	1/31/2018	Apotex 3.2.S.4.1 Specification - Tasimelteon - DMF #031843 (duplicate, marked in a different exhibit)	APO-TASI-0002423	APO-TASI-0002423	
150	2/3/2020	Letter to Apotex Corp. from S. Kurtz (FDA) re: ANDA Tentative Approval	APO-TASI-0131487	APO-TASI-0131492	
151	7/3/2019	Spreadsheet VNDA Long Range Plan - Cash P&L	VNDHTLZ 01190200	VNDHTLZ 01190200	
152	7/1/2019	Spreadsheet Vanda Pharmaceuticals Inc. - Hetlioz US Product P&L	VNDHTLZ 01190201	VNDHTLZ 01190201	
153	12/11/2016	Spreadsheet VNDA P&L - Consolidated GAAP	VNDHTLZ 01211630	VNDHTLZ 01211630	
154	6/7/1999	Report for Protocol No. CN116-002	VNDHTLZ 01301956	VNDHTLZ 01302256	

FOR THE DISTRICT OF DELAWARE

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155		Spreadsheet - Non R&D Data	VNDHTLZ 03081566	VNDHTLZ 03081566	
156		Spreadsheet - Vanda Pretax Cashflow	VNDHTLZ 03081567	VNDHTLZ 03081567	
157		Spreadsheet - Vanda P&L - Consolidated GAAP	VNDHTLZ 03081568	VNDHTLZ 03081568	
158		Spreadsheet - Hetlioz-Non-24-US	VNDHTLZ 03081569	VNDHTLZ 03081569	
159		Spreadsheet, Hetlioz Wave 2	VNDHTLZ 03099377	VNDHTLZ 03099377	
160		Spreadsheet, Hetlioz Wave 3	VNDHTLZ 03102837	VNDHTLZ 03102837	
161	2/28/2012	Takeda Pharm. Co., A Randomized, Double-Blind, Placebo-Controlled, Parallel, Proof Of Concept Study To Evaluate The Effectiveness Of Ramelteon To Advance The Timing Of Sleep In Individuals With Delayed Sleep Phase Syndrome (Dsps), Nct00593736			
162	3/31/2020	Surrogate Endpoint Resources for Drug and Biologic Development - FDA			
163	2019	Tubbs et al. Refractory Insomnia In An Adolescent With Total Blindness, 92 Yale Journal Of Biology And Medicine 201 (2019)			
164	3/4/2017	Australian Government Department of Health - Public Summary re: APO -MELATONIN MR melatonin 2 mg modified release tablet blister pack			

FOR THE DISTRICT OF DELAWARE

C.A. No. 18-00651-CFC

Vanda Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc., et al.

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165	3/4/2017	Australian Government Department of Health - Public Summary re: MELATONIN MR APOTEX melatonin 2 mg modified release tablet blister pack			
166	3/4/2017	Australian Government Department of Health - Public Summary re: CHEMMART MELATONIN MR melatonin 2 mg modified release tablet blister pack			
167	3/4/2017	Australian Government Department of Health - Public Summary re: TERRY WHITE CHEMISTS MELATONIN MR melatonin 2 mg modified release tablet blister pack			
168	3/4/2017	Australian Government Department of Health - Public Summary re: BLOOMS THE CHEMIST MELATONIN MR melatonin 2 mg modified release tablet blister pack			
169	10/2011	FDA, Guidance for Industry: Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products — Content and Format			
170	1998	Moltke et al. <i>In Vitro Approaches to Predicting Drug Interactions in Vivo</i> , Biochemical Pharmacology, Vol. 55, pp. 113-132			
171	8/16/2010	Greenblatt et al. <i>Sources of Variability in Ketoconazole Inhibition of Human Cytochrome P450 3A in Vitro</i> , Xenobiotica, 40:10, 713-720			
172	7/7/1905	Roth et al., "Prolonged Release Melatonin for Improving Sleep in Totally Blind Subjects: A pilot Placebo-Controlled Multicenter Trial," NATURE AND SCI. OF SLEEP 7:13-23 (2015)	TASI-DEF-0015132	TASI-DEF-0015142	

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

VANDA PHARMACEUTICALS
INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA,
INC., et al.,

Defendants.

C.A. No. 18-651-CFC
(Consolidated)

**Exhibit 13 – Brief Statement of Intended
Proofs in Support of Plaintiff's Claims**

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I. INTRODUCTION

1. A brief statement of what Plaintiff Vanda Pharmaceuticals, Inc. (“Vanda”) intends to prove in support of its claims at trial is set forth below. This statement is not exhaustive, and Vanda reserves the right to prove any matters identified in the pleadings, in interrogatory and other discovery responses, in its expert reports, and in the accompanying statements of the facts and legal issues to be litigated at trial.

2. Vanda may also provide additional proof(s) to rebut any alleged proof(s) offered by Defendants (i) Teva Pharmaceuticals USA, Inc. (“Teva”) and (ii) Apotex Inc. and Apotex Corp. (“Apotex”) (collectively, “Defendants”) before and during trial, in response to rulings by the Court, or for other good cause.¹

3. At trial, Vanda will assert U.S. Patents RE46,604 (the “RE604 patent”); 9,539,234 (the “’234 patent”); 10,149,829 (the “’829 patent”); 9,730,910 (the “’910 patent”); 10,376,487 (the “’487 patent”) (collectively, the “Asserted Method-of-Treatment Patents”); and 10,829,465 (the “’465 patent”) (collectively, with the Asserted Method-of-Treatment Patents, the “the Asserted Patents”).

¹ Plaintiff reserves the right to revise its statement of intended proofs based on Defendants’ revisions to the pretrial submissions, including the statement of uncontested facts or Defendants’ statements of contested issues of law or fact.

II. INFRINGEMENT OF THE ASSERTED PATENTS

A. The Method-of-Treatment Claims

4. Vanda will prove that Teva's submission of its Abbreviated New Drug Application No. 211601 to FDA, which includes its proposed tasimelteon drug substance and drug product and proposed labeling ("Teva's ANDA Product"), constitutes infringement of the Asserted Patents pursuant to 35 U.S.C. § 271(e)(2).

5. Vanda will prove that Apotex's submission of its Abbreviated New Drug Application No. 211607 to FDA, which includes its proposed tasimelteon drug substance and drug product and proposed labeling ("Apotex's ANDA Product"), constitute infringement of the Asserted Patents pursuant to 35 U.S.C. § 271(e)(2).

6. Vanda will prove by the preponderance of the evidence that Defendants will actively induce infringement of claim 3 of the RE604 patent; claim 4 of the '234 patent; claim 14 of the '829 patent; claim 4 of the '910 patent; and claim 5 of the '487 patent (collectively, the "Method-of-Treatment Claims") pursuant to 35 U.S.C. § 271(b) upon the sale and/or marketing of their ANDA Products.

7. Vanda will prove by the preponderance of the evidence that Defendants will contribute to the infringement of the Method-of-Treatment Claims pursuant to 35 U.S.C. § 271(c) upon the sale and/or marketing of their ANDA Products.

8. Vanda will prove by a preponderance of the evidence that Defendants' ANDA Products will directly infringe claim 10 of the '465 patent pursuant to 35 U.S.C. § 271(a).

9. Vanda will prove by a preponderance of the evidence that Defendants' ANDA Products will infringe claim 10 of the '465 patent pursuant to 35 U.S.C. § 271(g).

III. THE ASSERTED PATENTS ARE NOT INVALID

10. Vanda will show that a person of ordinary skill in the art relevant to claim 3 of the RE604 patent is a person or persons or team of people with experience treating individuals with circadian rhythm disorders, including a person or persons or team of people qualified to prescribe medication, or a person or persons or team of people with experience researching circadian rhythm disorders.

11. Vanda will show that a person of ordinary skill in the art relevant to claim 4 of the '234 patent; claim 14 of the '829 patent; claim 4 of the '910 patent; and claim 5 of the '487 patent is a person or persons or team of people having (1) a bachelor's degree and at least some laboratory experience in medicine, pharmacy, pharmacology, or a related field such as biochemistry, with experience with drug metabolism and/or drug-drug interactions, or at least some experience with preclinical and/or clinical drug development; and (2) experience treating individuals with circadian rhythm disorders, including a person or persons or team of people

qualified to prescribe medication, or experience researching circadian rhythm disorders.

12. Vanda will show that a person of ordinary skill in the art relevant to claim 10 of the '465 patent is a person, persons, or team of people having a bachelor's degree in chemistry, organic chemistry, medicinal chemistry, chemical engineering, pharmaceuticals, or a related discipline.

13. Vanda has no burden of proof regarding Defendants' invalidity defenses, but will offer rebuttal evidence showing that Defendants will not be able to prove, by clear and convincing evidence, that any of the claims of the Asserted Patents are anticipated (including anticipated by prior use, sale, or offer for sale), obvious, lack written description, lack enablement, or lack proper inventorship.

14. Vanda will also satisfy its burden of production on objective indicia of nonobviousness for the claims of the Asserted Patents.

15. Vanda will further rebut Defendants' evidence concerning on sale bar, including by demonstrating that any alleged prior sale or offer for sale of products embodying the claims of the Asserted Patents was for the purpose of experimentation, qualified as an experimental use, and occurred as a means of furthering research.

16. Vanda will further rebut Defendants' evidence by demonstrating that Defendants' asserted Clinical Trials reference reflects the experimental use of the subject matter of the Method-of-Treatment Claims.

IV. RELIEF

17. Vanda will show that this is an "exceptional case" under 35 U.S.C. § 285.

18. Vanda will show that it is entitled to an order that the effective date of any approval of Defendants' ANDA Products shall be a date not earlier than the expiration of the last-expiring patent held infringed and not invalid pursuant to 35 U.S.C. § 271(e)(4)(A).

19. Vanda will show that it is entitled to injunctive relief against each Defendant to prevent the commercial manufacture, use, offer to sell, or sale within the united States of importation into the United States of Defendants' respective ANDA Products prior to the expiration date of the last-expiring patent held infringed and not invalid pursuant to 35 U.S.C. § 271(e)(4)(B).

20. Vanda will show that it is entitled to a declaratory judgment that the commercial manufacture, use, offer for sale, sale and/or importation of Defendants' ANDA Products will infringe each asserted claim of the asserted patents, and that Defendants will induce infringement of each asserted claim of the Asserted Patents.

21. Vanda will show that it is entitled to costs and/or attorneys' fees.

22. Vanda will show that it is entitled to any other relief the Court may deem just and proper.

23. To the extent necessary, Vanda will rebut any allegation by Defendants that they, or any of them, are entitled to costs and/or attorneys' fees.

24. Vanda reserves the right to offer evidence in support of a claim of injunctive relief and will show that it is entitled to injunctive relief should Defendants contest such an injunction.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

VANDA PHARMACEUTICALS)	
INC.,)	
)	
Plaintiff,)	
)	C.A. No. 18-651-CFC
v.)	CONSOLIDATED
)	
TEVA PHARMACEUTICALS USA,)	
INC.,)	
)	
Defendant.)	

**EXHIBIT 14: DEFENDANTS’ BRIEF
STATEMENT OF INTENDED PROOFS**

Pursuant to Local Rule 16.3(c)(9), Defendants Apotex Inc. and Apotex Corp. (collectively, “Apotex”) and Teva Pharmaceuticals USA, Inc. (“Teva”) (collectively, “Defendants”) submit the following brief statement of the primary matters Defendants intend to prove at trial. This statement is not exhaustive, and Defendants reserve the right to prove any matter identified in their pleadings, discovery responses, expert reports, and the accompanying statements of issues of facts and issues of law that remain to be litigated at trial. Defendants may also provide additional proof to rebut any proof offered by Plaintiff Vanda Pharmaceuticals Inc. before and during trial, in response to rulings by the Court, or for other good cause. Defendants reserve the right to modify or amend this

Statement to the extent necessary to reflect any future rulings by the Court, and to supplement or amend this Statement to fairly respond to any new issues that Plaintiff may raise. Defendants incorporate by reference their expert reports in support of any proof to be presented by expert testimony.

I. OVERVIEW OF NON-INFRINGEMENT

Plaintiff bears the burden of proving infringement by a preponderance of the evidence. Defendants will show that the products that are the subject of Teva's ANDA No. 211601 and Apotex's ANDA No. 211607 do not infringe:

- Claim 10 of U.S. Patent No. 10,829,465 (“the ’465 patent”);
- Claim 3 of U.S. Patent No. RE46,604 (“the ’604 patent”);
- Claim 4 of U.S. Patent No. 9,539,234 (“the ’234 patent”);
- Claim 14 of U.S. Patent No. 10,149,829 (“the ’829 patent”); and
- Claim 4 of U.S. Patent No. 9,730,910 (“the ’910 patent”) (collectively, “Asserted Patents”).

Plaintiff bears the burden of proving direct infringement by a preponderance of the evidence. Plaintiff cannot show by a preponderance of the evidence that Defendants' submissions to the U.S. Food & Drug Administration (“FDA”) of ANDA Nos. 211601 and 211607 were acts of infringement of the claims of the Asserted Patents. Plaintiff also cannot show by a preponderance of the evidence that the manufacture, use, offer for sale, marketing, distribution and/or importation

of the proposed drug product described in ANDA Nos. 211601 and 211607 will infringe the claims of the Asserted Patents.

Plaintiff bears the burden of proving induced infringement, under 35 U.S.C. § 271(b), by a preponderance of the evidence. Plaintiff cannot show by a preponderance of the evidence that [REDACTED], or [REDACTED], will directly infringe the '465 patent or that patients and healthcare providers will directly infringe the remaining Asserted Patents.

Plaintiff bears the burden of proving contributory infringement, under 35 U.S.C. § 271(c), by a preponderance of the evidence. Plaintiff cannot show by a preponderance of the evidence that [REDACTED], or [REDACTED], will directly infringe the '465 patent or that patients and healthcare providers will directly infringe the remaining Asserted Patents.

The evidence of non-infringement of the '465 patent will consist primarily of Defendants' own documents and testimony by Defendants' expert, Dr. Robert Perni.

The evidence will show, *inter alia*, that:

1. [REDACTED]
[REDACTED]
[REDACTED];

2. [REDACTED]

[REDACTED]

[REDACTED];

3. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED];

4. [REDACTED]

[REDACTED]

[REDACTED];

5. [REDACTED]

[REDACTED].

The evidence of non-infringement of the remaining Asserted Patents will consist primarily of Defendants' own documents and testimony by Defendants' experts, Drs. Deborah Jaskot and John Winkelman.

The evidence will show, *inter alia*, that:

1. Defendants' labels do not instruct physicians to administer tasimelteon to entrain a patient's sleep-wake cycle, cortisol circadian rhythm, or melatonin circadian rhythm;

2. [REDACTED]

3. Plaintiff admits that using tasimelteon to entrain patients is not included in the Hetlioz® label (or Defendants' labels);

4. Plaintiff's correspondence with FDA will show that Plaintiff proposed using entrainment as a primary endpoint for its clinical testing of tasimelteon and sought to include entrainment in the Hetlioz® label, but FDA rejected Plaintiff's proposals.

5. Plaintiff's correspondence with FDA confirms that tasimelteon is indicated only for the treatment of clinical symptoms of Non-24, not entrainment; and

6. [REDACTED]

II. OVERVIEW OF INVALIDITY

A. Person of Ordinary Skill

Defendants intend to prove that a person of ordinary skill in the art as of the priority date for the '465 patent has the following background:

1. An advanced degree, such as a Ph.D. in organic chemistry, medicinal chemistry, chemical engineering, pharmaceuticals, or a related discipline, along with several years of experience working in the field;

2. Alternatively, an undergraduate or Master's degree with an emphasis of study in a similar discipline and have considerable experience working in the field;

3. In general, the person (or team) of ordinary skill in the art could have had a lower level of formal education if such a person (or team) had a higher degree of experience in the field;

4. Knowledge or awareness of relevant regulatory considerations concerning the approval of pharmaceutical products for human use and regulatory considerations concerning the commercial manufacture of pharmaceutical products, such as cGMP standards, ICH guidelines, FDA Guidelines, and the like;

5. A person of ordinary skill could have worked as part of a multi-disciplinary team and could have had access to and drawn upon the knowledge of individuals with comparable levels of education and experience in relevant disciplines that lie outside his or her primary training; and

6. The person (or team) of ordinary skill would easily have understood the disclosure and import of the prior-art references, and would have had the capacity to draw inferences from the prior art and from others in the field.

Defendants intend to prove that a person of ordinary skill in the art as of the priority dates of the remaining Asserted Patents would have been:

1. A medical doctor with at least 2-3 years of post-residency experience and/or training in the diagnosis and treatment of patients with sleep disorders and/or circadian rhythm disorders, and in particular education, training and/or clinical experience in the treatment of Non-24;
2. Familiar with and may have consulted with other persons of ordinary skill with experience developing or characterizing drugs, running clinical trials, and researching the clinical pharmacology of drugs; and
3. For some claims, experienced and/or knowledgeable in the area of drug metabolism, pharmacokinetics, and pharmacology; and
4. Could have worked as part of a multi-disciplinary team and could have had access to and drawn upon the knowledge of individuals with comparable levels of education and experience in relevant disciplines that lie outside his or her primary training.

B. Invalidity Based on the On-Sale Bar Under 35 U.S.C. § 102(b)

Defendants intend to prove that Plaintiff, [REDACTED]

[REDACTED]

[REDACTED] offered for sale and sold batches of tasimelteon claimed by the '465

patent before its priority date. The evidence will consist primarily of Plaintiff's own documents and testimony by Defendants' expert, Dr. Robert Perni.

The evidence will show, *inter alia*, that:

1. Before the priority date of the '465 patent, Plaintiff was offered for sale and sold tasimelteon batches— [REDACTED]

[REDACTED]

[REDACTED].

2. At least some of the tasimelteon b [REDACTED]
[REDACTED] were intended for use in clinical trials or commercial sale.

3. The listed Impurities 1–3 and 5–7 of the specification for [REDACTED]
[REDACTED] correspond to what the '465 patent terms Impurities 1–3 and 5–7.

4. Tasimelteon batch [REDACTED]
[REDACTED] were tested and demonstrated to contain, *inter alia*, NMT 0.15% (w/w) of Impurities 1–3 and 5–7 and NMT 0.10% of any unidentified impurity (which includes Impurity 4).

5. Tasimelteon batch [REDACTED]
[REDACTED] were made according to what Vanda's New Drug Application No. 205677 references as Process 8.

6. Process 8 includes the reduction and propionylation steps of the '465 patent to synthesize tasimelteon.

7. Before the priority date of the '465 patent, Plaintiff purchased tasimelteon batches pursuant to [REDACTED].

8. The listed Impurities 1–3 and 5–7 of the specification for [REDACTED] correspond to what the '465 patent terms Impurities 1–3 and 5–7.

9. [REDACTED] required that tasimelteon be manufactured with no more than 0.15% (w/w) of Impurities 1–3 and 5–7 and no more than 0.10% a/a of any single unidentified impurity (including Impurity 4).

10. The manufacturing process associated with [REDACTED] included the reduction and propionylation steps of the '465 patent to synthesize tasimelteon.

11. To the extent that Plaintiff offers evidence that these offers for sale and sales of tasimelteon constitute experimental use, Defendants intend to offer proof that the requirements for experimental use are not met.

C. Obviousness Under 35 U.S.C. § 103

1. '465 Patent

Defendants expect to rely on, among others, the following prior art combinations to establish that the asserted claims of the '465 patent are obvious:

1. CN 102675268 A (“CN ’268”) in view of the ICH Harmonized Tripartite Guideline, titled “Impurities in New Drug Substances Q3A(R2)” (“ICH Q3A Guideline”);

2. “Factors Influencing the Application of Literature Methods Toward the Preparation of a Chiral trans-Cyclopropane Carboxylic Acid Intermediate During Development of a Melatonin Agonist,” authored by Ambarish K. Singh, et al. (“Singh”) in view of the ICH Q3A Guideline; and

3. U.S. Patent No. 5,856,529 (“’529 patent”) in view of the ICH Q3A Guideline.

The evidence will consist primarily of the cited prior art references and testimony of Defendant’s expert, Dr. Robert Perni.

The evidence will show, *inter alia*, that:

1. For each of these combinations, a person of ordinary skill would have been motivated to combine the individual references;

2. For each of these combinations, a person of ordinary skill would have had a reasonable expectation of success in combining their teachings;

3. A person of ordinary skill would have found it obvious to perform the claimed reduction step to synthesize tasimelteon;

4. A person of ordinary skill would have found it obvious to perform the claimed propionylation step to synthesize tasimelteon;

5. A person of ordinary skill would have found it obvious to synthesize tasimelteon with NMT 0.15 wt% of each of Impurities 5 and 6;

6. A person of ordinary skill would have found it obvious to synthesize tasimelteon with NMT 0.15 wt% of each of Impurities 1, 2, and 3;

7. A person of ordinary skill would have found it obvious to synthesize tasimelteon with NMT 0.15 wt% of each of Impurities 4 and 7;

8. It would have been obvious to a person of ordinary skill that the synthesis of tasimelteon can result in the formation of impurities, such as Impurities 1–7;

9. A person of ordinary skill would have analyzed any pharmaceutical product for impurities, regardless of whether those impurities were specifically known or whether their structure had been determined;

10. A person of ordinary skill would have found it obvious to look to regulatory guidance, such as the ICH Q3A Guideline, to set thresholds for impurities for a pharmaceutical product;

11. The ability to detect Impurities 1–7 was within the general background of a person of ordinary skill;

12. Methods, such as High Performance Liquid Chromatography (HPLC), commonly used to detect and characterize impurities in a drug substance were sensitive enough to detect Impurities 1–7;

13. To perform an HPLC analysis, it was not necessary to know the identity of an impurity ahead of time;

14. A person of ordinary skill would have understood that the analytical tests available to test for impurities would detect impurities that are unknown as well as known;

15. The claims of the '465 patent do not require characterization of the structure (i.e. "identification") of Impurities 1–7; and

16. At least Impurity 4 was known from disclosures in the prior art.

2. Method of Treatment Patents

Defendants expect to rely on, among others, the following prior art references to establish that the claims of the Asserted Patents (other than the '465 patent) as well as claims 1 and 5 of U.S. Patent No. 10,376,487 ("the '487 patent") and claims 1 and 5 of U.S. Patent No. 10,610,511 ("the '511 patent") (collectively, the "Asserted Method of Treatment Patents") are obvious:

1. Clinical trial protocol titled "Efficacy and Safety of Tasimelteon Compared With Placebo in Totally Blind Subjects With Non-24-Hour Sleep-Wake Disorder" ("Clinical Trials");

2. "Tasimelteon for insomnia," authored by Dr. Alan Lankford ("Lankford");

3. “The Effects of Low-Dose 0.5-mg Melatonin on the Free-Running Circadian Rhythms of Blind Subjects,” authored by Lisa M. Hack, et al. (“Hack”);
4. WO Patent No. 2007/137244 A1, titled “Melatonin Agonist Treatment” (“’244 Publication”);
5. “New approaches in the management of insomnia: weighing the advantages of prolonged-release melatonin and synthetic melatoninerbic agonists,” authored by Rudiger Hardeland (“Hardeland I”);
6. “Melatonin agonist tasimelteon (VEC-162) for transient insomnia after sleep-time shift: two randomized controlled multicenter trials,” authored by Shantha M W Rajaratnam, et al. (“Rajaratnam”);
7. “Cytochrome P450 and Drug Interactions,” authored by D.K. Badyal and A.P. Dadhich (“Badyal”);
8. “The Effect of Cytochrome P450 Metabolism on Drug Response, Interactions, and Adverse Effects,” authored by T. Lynch et al. (“Lynch”)
9. “Pharmacotherapy of Insomnia with Ramelteon: Safety, Efficacy and Clinical Applications,” authored by Seithikurippu R. Pandi-Perumal, et al. (“Pandi-Perumal”); and
10. “Metabolism of Ramelteon in Human Liver Microsomes and Correlation with the Effect of Fluvoxamine on Ramelteon Pharmacokinetics,” authored by R. Scott Obach and Tim F. Ryder (“Obach”).

Defendants intend to prove how the following combinations of these references establish that the claims of the Asserted Method of Treatment Patents are obvious:

1. Clinical Trials, Lankford, Hack, and/or '244 Publication;
2. '244 publication, Hardeland, Hack, and/or Rajaratnam;
3. Clinical Trials, Lankford, Hack, '244 publication, Hardeland, Badyal, and/or Lynch;
4. '244 publication, Hardeland, Hack, Rajaratnam, Badyal, and/or Lynch;
5. Clinical Trials, Lankford, Hack, and '244 publication, Hardeland, Pandi-Perumal, and/or Obach; and
6. '244 publication, Hardeland, Hack, Rajaratnam, Pandi-Perumal, and/or Obach.

The evidence will consist primarily of the testimony of Defendants' experts, Drs. Jonathan Emens and David Greenblatt.

The evidence will show, *inter alia*, that:

1. For each of these combinations, a person of ordinary skill would have a motivation to combine the individual references;
2. For each of these combinations, a person of ordinary skill would have had a reasonable expectation of success in combining their teachings;

3. A person of ordinary skill would have found it obvious, and would have been motivated to entrain a totally blind patient suffering from Non-24 to a 24 hour sleep-wake cycle in which the patient awakens at or near a target wake time following a daily sleep period of approximately 7 to 9 hours, and maintaining said 24 hour sleep-wake cycle by treating the patient by orally administering to the patient 20 mg of tasimelteon once daily 0.5 to 1.5 hours before a target bedtime;

4. A person of ordinary skill would have found it obvious, and would have been motivated to treat a light perception impaired patient for Non-24-Hour Sleep-Wake Disorder by treating the patient with tasimelteon 0.5 to 1.5 hours before the target sleep time;

5. A person of ordinary skill would have found it obvious, and would have been motivated to treat a light perception impaired patient for Non-24-Hour Sleep-Wake Disorder by orally administering to the patient 20 mg of tasimelteon once daily before a target bedtime;

6. A person of ordinary skill would have found it obvious, and would have been motivated to treat a patient for Non-24-Hour Sleep-Wake Disorder by treating the patient with 20 mg of tasimelteon once daily;

7. A person of ordinary skill would have found it obvious, and would have been motivated to determine if a patient was being treated with a CYP1A2

inhibitor, including fluvoxamine, ciprofloxacin, and verapamil, prior to treating the patient with tasimelteon;

8. A person of ordinary skill would have found it obvious, and would have been motivated to reduce the dosage of, or discontinue administration of, a CYP1A2 inhibitor and/or a CY3A4 inducer prior to administering tasimelteon to a patient;

9. A person of ordinary skill would have found it obvious and would have been motivated to reduce the dose of, or discontinue the administration of, fluvoxamine, ciprofloxacin, verapamil (CYP1A2 inhibitors) prior to treating a patient with tasimelteon;

10. A person of ordinary skill would have found it obvious and would have been motivated to discontinue the administration of rifampicin (a CY3A4 inducer) prior to treating a patient with tasimelteon;

11. A person of ordinary skill would have reasonably expected that by discontinuing treatment with a strong CYP1A2 inhibitor prior to treating a patient with tasimelteon, one could successfully avoid the use tasimelteon in combination with the strong CYP1A2 inhibitor;

12. A person of ordinary skill would have reasonably expected that by reducing the dose of a strong CYP1A2 inhibitor prior to treating a patient with tasimelteon, one could successfully reduce the exposure to tasimelteon;

13. A person of ordinary skill would have reasonably expected that by avoiding the use of rifampicin (a CYP3A4 inducer) in combination with tasimelteon, one could successfully avoid reduced exposure to tasimelteon resulting from induction of CYP3A4 by rifampicin;

14. A person of ordinary skill would have found it obvious, and would have been motivated to administer a daily dose of 20 mg tasimelteon without food to a patient suffering from a CRSD or sleep disorder, and more specifically, to a patient suffering from Non-24; and

15. A person of ordinary skill would have found it obvious, and would have been motivated to instruct a patient suffering from a CRSD or sleep disorder, and more specifically, to instruct a patient suffering from Non-24, to administer an effective dose of tasimelteon without food.

3. Secondary Considerations

To the extent that Plaintiff offers evidence of any secondary considerations of non-obviousness for the '465 patent or any of the Asserted Method of Treatment Patents, Defendants intend to offer proof that no such considerations support a finding of non-obviousness.

The evidence will consist primarily of the testimony of Defendants' experts, Drs. DeForest McDuff, Jonathan Emens, and Robert Perni.

The evidence will show, *inter alia*, that:

1. Plaintiff's secondary considerations position relies on flawed analysis of Hetlioz®'s product performance, which shows weak commercial performance and is not indicative of a commercially successful product;

2. Plaintiff's secondary considerations position relies on a flawed and incomplete analysis of nexus;

3. a blocking patent reduces the relevance of alleged indicia of nonobviousness (if any);

4. Vanda's development timeline does not provide reliable economic evidence that the Asserted Method of Treatment Patents and the '465 patent are not obvious;

5. there is no evidence of long-felt need, failure of others, praise, skepticism, unexpected results, or copying by others;

6. One cannot conclude that tasimelteon has fulfilled a treatment need that was left unmet by melatonin, which has been identified as an effective treatment for Non-24;

7. There is no evidence that tasimelteon provide a significant improvement in safety or effectiveness over melatonin;

8. One cannot conclude that tasimelteon has fulfilled a treatment need, particularly because very few patients actually take tasimelteon to treat Non-24;

9. Hetlitz® has not satisfied any real world need (assuming one exists) for treatment of “another CRSD” (circadian rhythm sleep disorder);

10. The relevance of alleged “failure of others” is diminished by the fact that only Vanda had a license to use tasimelteon;

11. Studies by BMS are not evidence of failure of others as [REDACTED]
[REDACTED];

12. If failure to obtain FDA approval for tasimelteon for the treatment of something *other* than Non-24 is failure, then the inventors themselves also failed;

13. Ramelteon is not considered a failure of others, particularly as there are no clinical studies of its use for the treatment of Non-24;

14. Circadin® (prolonged release melatonin) tablets is not considered a failure of others, particularly because it is a prolonged release melatonin product, which is different from the immediate release formulations and any debate about the correct timing and dosage of Circadin® is simply about the optimal regimen for melatonin treatment;

15. Given the state of the prior art, there is nothing unexpected about tasimelteon’s effects in Non-24 patients when administered according to the asserted claims; and

16. The SET and RESET trials do not support a finding of unexpected results as they only compared tasimelteon to placebo, not to melatonin.

In addition to rebutting any such alleged secondary considerations, Defendants reserve their right to present additional proof in rebuttal to Plaintiff's response.

D. Anticipation Under 35 U.S.C. § 102

Defendants intend to prove at trial that:

1. Clinical Trials anticipates:
 - a. claim 3 of the '604 patent;
 - b. claims 1 and 5 of the '487 patent; and
 - c. claims 1 and 5 of the '511 patent.
2. Lankford anticipates:
 - a. claims 1 and 5 of the '487 patent; and
 - b. claims 1 and 5 of the '511 patent.
3. '244 publication anticipates:
 - a. claims 1 and 5 of the '487 patent; and
 - b. claims 1 and 5 of the '511 patent.
4. Hardeland anticipates:
 - a. claims 1 and 5 of the '487 patent; and
 - b. claims 1 and 5 of the '511 patent.

The evidence will consist primarily of the cited prior art and testimony by Defendants expert, Dr. Jonathan Emens.

E. Inventorship

Defendants intend to prove that the named inventors on the '465 patent did not invent one or more limitations claimed in the '465 patent. The evidence will consist primarily of Plaintiff's own documents, the testimony of the named inventors, and testimony by Defendants' expert, Dr. Robert Perni.

The evidence will show, *inter alia*, that:

1. Tasimelteon was first discovered and manufactured by Bristol Myers Squibb Co. (BMS);

2. Prior to Vanda's involvement with tasimelteon, BMS had conceived of the process for synthesizing tasimelteon the appears in the claims of the '465 patent;

3. Prior to Vanda's involvement with tasimelteon, BMS had conceived of the tasimelteon product that appears in the claims of the '465 patent;

4. Prior to Vanda's involvement with tasimelteon, BMS had manufactured a batch of tasimelteon using the process that appears in the claims of the '465 patent and meeting the impurity thresholds of the patent;

5. BMS [REDACTED]

[REDACTED]

[REDACTED] on which Vanda

based the claims of the '465 patent;

6. BMS had found and knew of at least Impurities 4, 5, and 7 that appear in the claims of the '465 patent;

7. BMS's IND submission shows at least the reduction and propionylation reactions that appear in the claims of the '465 patent;

8. The named inventors on the '465 patent did not invent or discover each of Impurities 1–7;

9. The named inventors on the '465 patent chose 0.15% as the specification for Impurities 1–7 because of disclosures in the ICH Guidelines;

10. Tentative identification of an impurity constitutes conception of the structure but lacks only definitive proof of structure, which can be accomplished through routine experimentation;

11. Vanda relied on [REDACTED] to propose and confirm structures for the impurities that are listed in the manufacturing specification;

12. [REDACTED] conducted the identification work for impurities proposed by Vanda;

13. One or more of the named inventors were aware that Impurity 4 was known in the prior art as of the priority date of the '465 patent;

14. One of the named inventors (Natalie Farris) was not involved in any kind of identification work as related to the impurities of the '465 patent; and

15. Vanda's alleged investment in developing the process used to manufacture its drug substance does not indicate that Vanda conceived of the alleged inventions in the '465 patent.

F. Written Description and Enablement

Defendants will show that claims 1 and 5 of the '487 patent and claims 1 and 5 of the '511 are invalid under 35 U.S.C. § 112 for lack of written description or as not enabled. The evidence will consist primarily of testimony by Defendants' expert, Dr. Jonathan Emens.

The evidence will show, *inter alia*, that:

1. Several claims of the Asserted Method of Treatment Patents are not limited to administering tasimelteon to Non-24 patients but instead include administration to a broader group of patients with other CRSDs or sleep disorders;
2. Certain claims provide no details about or restrictions on the dosing regimen to be used;
3. Certain claims cover the use of amounts other than 20 mg, at times other than before a target bedtime, by means other than oral administration, and at frequencies other than once daily;
4. To the extent that Vanda suggests that certain claims are inventive in whole or in part because the addition of the "without food" limitation creates a

method of treatment that is more efficacious in Non-24 patients than giving the drug with food, the specifications do not describe such a method;

5. The patent specifications do not enable or disclose such administration.

III. OVERVIEW OF REMEDIES/DAMAGES

If the '465 patent or any of the Asserted Method of Treatment Patents are found to be valid and infringed, Plaintiff cannot show that it would be entitled to an injunction because, among other things, Plaintiff has an adequate remedy at law.

If the '465 patent or any of the Asserted Method of Treatment Patents are found to be valid and infringed, Plaintiff cannot show that it would be entitled to pre-judgment and post-judgment interest and costs.

IV. OVERVIEW OF ATTORNEYS FEES

If the '465 patent or any of the Asserted Method of Treatment Patents are found to be valid and infringed, Plaintiff cannot show that it would be entitled to attorneys' fees because this is not an exceptional case.

Defendants are entitled to attorneys' fees because this is an exceptional case on Vanda's part.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

VANDA PHARMACEUTICALS
INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA,
INC., et al.,

Defendants.

C.A. No. 18-651-CFC
(Consolidated)

Exhibit 15 – Plaintiff’s Statement of Additional Matters

1. The parties agree that Plaintiff's expert Dr. Henry G. Grabowski may testify remotely at trial.

2. On February 16, 2022—less than two and one-half hours before the filing of this Joint Proposed Pretrial Order—Defendants disclosed to Vanda for the first time that they intend to include on their exhibit list “a declaration relating to the public availability of the clinical trial protocol summary” that Defendants contend is prior art to the asserted method-of-treatment claims in this case. Vanda objects to any such declaration as untimely and highly prejudicial. The deadline for the close of fact discovery was July 30, 2021, and the deadline for the close of expert discovery was December 17, 2021. Yet Defendants did not disclose until today (when the [Proposed] Joint Pretrial Order is due to the Court) their intention to obtain such a declaration, and they still have not disclosed the contents of such declaration, the identity of the would-be declarant, or any expert opinions relating to facts that will be attested to in the declaration. Instead, Defendants merely state that they are “reserving a spot on our exhibit list to supply a declaration on that issue” at some later, unspecified time. Vanda has thus not had the opportunity to assess the accuracy of any facts that will be disclosed in the declaration and has not had an opportunity to depose Defendants' would-be declarant as to any statements in the declaration. Additionally, to the extent Defendants intend to introduce expert testimony as to the facts that will be contained in the declaration,

Defendants have not disclosed such expert opinions, Vanda's experts have not had a chance to respond to such expert opinions, and Vanda has not had the opportunity to depose Defendants' expert(s) about such opinions. Defendants attempt to justify the untimely disclosure of this declaration—on an issue on which Defendants bear the burden of proof—by claiming that they were not aware that this issue was in dispute, despite Vanda having raised it numerous times throughout fact and expert discovery. *See, e.g.*, June 11, 2021, Vanda's Objs. and Resps. to Defs. First Set of Interrogs. to Vanda (Nos. 1-5) Regarding U.S. Patent Nos. 10,610,510; 10,610,511; 10,829,465; and 10,611,744 at 27-28 ("Furthermore, Defendants have not established the 'public' nature of the alleged Clinical Trials reference or that the information disclosed in Defendants' alleged reference was actually contained in whatever was originally posted to clinicaltrials.gov"); July 3, 2019, Vanda's Objs. and Resps. to Defs. First Set of Joint Interrogs. to Vanda (Nos. 1-10) at 10, 16 ("Furthermore, Defendants have not established the 'public' nature of the alleged Clinical Trials reference."); Dec. 15, 2021, Dep. Tr. of Czeisler Dep. 175:13-179:24. Vanda's expert, Dr. Charles Czeisler, also made clear in his September 29, 2021 rebuttal expert report that he does not accept the publication date alleged by Defendants. September 29, 2021 Supplemental Expert Report of Charles A. Czeisler Ph.D., M.D., F.R.C.P., F.A.P.S. ¶ 83. Accordingly,

Defendants should not be permitted to introduce or rely upon on their proposed declaration.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

VANDA PHARMACEUTICALS)	
INC.,)	
)	
Plaintiff,)	
)	C.A. No. 18-651-CFC
v.)	CONSOLIDATED
)	
TEVA PHARMACEUTICALS USA,)	
INC.,)	
)	
Defendant.)	

EXHIBIT 16: DEFENDANTS’ STATEMENT OF ADDITIONAL MATTERS

Defendants Apotex Inc. and Apotex Corp. (collectively, “Apotex”) and Teva Pharmaceuticals USA, Inc. (“Teva”) (collectively, “Defendants”) submit the following statement of additional matters they would like to discuss at the pretrial conference. Defendants reserve the right to modify or amend this statement to the extent necessary to address any developments or issues that may arise or become apparent after its submission.

1. Due to an unexpected scheduling issue, one of Defendants’ experts, Dr. David Greenblatt, will not be available to testify until Thursday, March 31. Defendants thus respectfully request that Dr. Greenblatt’s testimony be permitted to take place on Thursday, March 31 or Friday, April 1.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

VANDA PHARMACEUTICALS INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.,
et al.,

Defendants.

C.A. No. 18-651-CFC
(Consolidated)

Exhibit 17 – Plaintiff’s Experts’ Curriculum Vitae

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Andrew Parkinson, Ph.D. Curriculum Vitae	F

Tab A

STEPHEN C. BERGMEIER

Curriculum Vitae

July 2021

Department of Chemistry & Biochemistry

205 Chemistry Building

Ohio University

Athens, Ohio 45701

Office: (740)-597-9649

Mobile: (740)-517-8462

email: bergmeis@ohio.edu

EXPERIENCE

Professor, September 2009 – Current

Department Chair, January 2014 – Current

- Represent department to the College of Arts & Sciences through regular meetings with the dean
- Manage a budget of >\$4M
- Seven direct reports + Graduate and Undergraduate Chairs
- Coordinate annual faculty review
- Support department wide research grants
- Advocate for and support new faculty searches
- Provide oversight of new building construction

Graduate Chair, October 2008 – December 2013.

- Administer a budget of >\$800,000 for the support of graduate students and graduate student recruitment.
- Set graduate student policies
- Approve graduate student contracts, process admissions, and monitor graduate student progress.
- Develop new degree programs (4+1, BS to MS degree)

Associate Professor (Awarded tenure in 2003)

Department of Chemistry and Biochemistry

Ohio University, Athens, Ohio

July 2000 – Current

NanoBioTechnology Initiative Executive Committee

Co-Chair: July 2005– Summer 2007

One of three co-chairs of a multi-department, multi-college research initiative. In the summer of 2007 this group was split into its three constituent groups (BMIT, BNNT, and DRI)

- Set priorities,
- Managed ~\$6,000,000 in funds to over 30 investigators.
- provided regular updates to the VP for research.

BioMolecular Innovation and Technology (BMIT) project.

Chair: Summer 2007 – August 2010. Directed a multi-department, multi-college research initiative.

- Set priorities
- Manage funds to over 15 investigators,
- Provided regular updates to VP for research.

Visiting Professor

Fakultät für Chemie und Mineralogie
Institut für Organische Chemie
Universität Leipzig, Leipzig, Germany
June – July, 2004, June 2007 – January 2008

CoFounder & Member of the Board of Directors

Promiliad Biopharma (Startup biotech company focused on the discovery of new antibacterial agents)

September 2002 – current

- Co-PI on NIH Phase I STTR, 1 Phase 1 SBIR, and Phase II STTR grants
- Successfully sought venture funding
- Developed collaborative relationships with other companies and universities.

Assistant Professor

Division of Medicinal Chemistry, College of Pharmacy,
The Ohio State University, Columbus, Ohio
September 1993 – June 2000.

Postdoctoral Fellow

University of California, Berkeley
January 1991 – August 1993
American Cancer Society Fellow
Working with Dr. Henry Rapoport.

Associate Scientist, Medicinal Chemistry

Warner-Lambert/Parke-Davis Pharmaceutical Research, Ann Arbor, Michigan
September 1982 – September 1987.

RESEARCH

Active Research Support

National Institutes of Health

Novel Glycogen Synthase Kinase-3 (GSK-3) Inhibitors as Therapeutic Agents

\$300,000 – direct costs, September 2016 – August 2023, Co-I

National Institutes of Health

R15 AREA: Optimizing allosteric modulation of noncoding regulatory RNA function

\$300,000 – direct costs, April 2019 – March 2022, Co-I

National Science Foundation

Controlling protein - protein interactions: computations and experiments

\$298,013 – direct costs, July 2020 – June 2023, Co-I

National Science Foundation

MRI: Acquisition of a matrix-assisted laser desorption/ionization time-of-flight mass spectrometer to enhance research and education

\$371,350 – direct costs, September 2020 – August 2023, PI

Past Research Support

National Science Foundation

MRI: Acquisition of a high resolution Orbitrap Q-Exactive Plus LC-MS/MS system for enhancing research and education

\$496,348 – direct costs, July 2014 – June 2015, PI

Advanced Drug Development in Oncology

Ohio Department of Higher Education

\$13,500 – direct costs, May 2016 – April 2017, PI

National Institutes of Health

Treating a Novel Regulatory RNA with Novel Antibiotics

\$1,556,006 – direct costs, January 2007 – January 2014, Co-PI

US – Egypt Joint Board on Scientific and Technological Cooperation

Novel diterpene derivatives as anticancer agents

\$113,636 direct costs, July 2011 – September 2014

National Institutes of Health, Phase II STTR (Interthyr Inc.)

TLR Signal Inhibition: A Novel Therapeutic Paradigm

\$166,728 – direct costs (Bergmeier), September 2009 – November 2011, Co-I

National Institutes of Health

Design and synthesis of novel antiviral agents

\$28,148 direct costs, January 2011 – December 2012

National Science Foundation

Partnerships for Innovation Project

Synthesis of Natural Product Inspired Combinatorial Libraries, PI

~\$40,000 – direct costs, September 2008 – August 2009

Ohio University Research Priority Initiative

NanoBioTech Initiative

~\$6,000,000 – direct costs, March 2005 – April 2010, Co-PI

The Hershey Corporation

Chiral Separation of Catechin and Epicatechin

\$13,770 – direct costs, January 2009 – December 2009

Diagnostic Hybrids

Synthesis of Nicotine Haptens

\$6,755 – direct costs, January 2006 – June 2006

National Institutes of Health - NIDA

Analogues of Methyllaconitine as Nicotinic Agents

\$946,800 - direct costs, January 2002 - July 2007, PI

National Institutes of Health, Phase I STTR

Fermentation Initiated Antibiotic Synthesis

\$55,480 – direct costs, September 2005 – July 2007, PI

National Science Foundation

Partnerships for Innovation Project,

Synthesis of Natural Product Inspired Combinatorial Libraries, PI

\$33,850 – direct costs, July 2005 – June 2006

Southeastern Ohio Science and Technology Commercialization Initiative (SOSCI)

Oxazolidinones as RNA binding antibacterials

\$113,784 – direct costs, July 2004 – December 2006, Co-PI

National Science Foundation

Studies in Aziridine-Allylsilane Cyclizations

\$222,000 – direct costs, March 1999 - January 2004, PI

Ohio University Research Council

Stereochemical Studies of Methyllaconitine Analogues

\$8,000 – purchase of a spectropolarimeter, January 2002, PI

National Institutes of Health - NIDA

Analogues of Methyllaconitine as Nicotinic Agents

\$99,956 – direct costs, August 1999 - July 2001, PI

American Chemical Society - Petroleum Research Fund

Solid Phase Synthesis Utilizing Acylnitrenes. Applications to the Synthesis of Hydroxyamino Acids

\$20,000, September 1997 – August 1999, PI

American Cancer Society, IRG Starter Grant

Combinatorial Synthesis of Bestatin Analogs

\$10,000, August 1997 – July 1998, PI

American Association of Colleges of Pharmacy

Synthesis of Analogs of Anticancer Pseudodistamin Alkaloids

\$10,000, December 1996 – November 1997, PI

American Cancer Society, Ohio Division.

Synthesis and Evaluation of poly(5-Aminopentanoic Acid Nucleobases) as Anticancer Agents.

\$19,998, August 1996 – July 1997, PI

TEACHING

Ohio University teaches classes on the semester system – two 15-week quarters during the regular academic year. I regularly teach one class per semester in the area of organic chemistry. Typically this entails at least one large undergraduate class as part of the organic chemistry sequence and at least one graduate class as part of the graduate organic chemistry sequence. Listed below are the courses that I have taught.

Ohio University – Chemistry 5600, Advanced Organic Chemistry, 6-10 graduate students, fall semester. The first semester of a three semester advanced organic chemistry sequence. The focus is on mechanisms, conformational analysis and physical organic chemistry.

Ohio University – Chemistry 701, Advanced Organic Chemistry. 6-10 graduate students, spring semester, second semester of a three semester advanced organic chemistry sequence. Study of modern synthetic methods and their application to the synthesis of complex molecules. Focus on oxidations, reductions and enolate chemistry.

Ohio University – Chemistry 7100, Special Topics in Organic Chemistry, Drug Action and Drug Design. 3-6 graduate students, fall semester. An introduction to the study of medicinal chemistry focusing on drug design, drug-macromolecule interactions and drug metabolism.

Ohio University – Chemistry 7050, Organometallic Chemistry. 6-10 graduate students, fall semester. This course covers the use of organometallic reagents in organic synthesis. This is a topical class with significant information from the current literature discussed.

Chemistry 7100, Special Topics in Organic Chemistry, Heterocyclic Chemistry. This course provides an overview of heterocyclic chemistry, including general methods for the synthesis and transformations of common heterocyclic ring systems.

Universität Leipzig, Institute of Organische Chemie, Leipzig, Germany. Medicinal Chemistry of Antimicrobial Agents. 12 PhD and diploma students. As part of the Ohio University – Universität Leipzig exchange program this course was taught in 2004. A thorough study of modern antimicrobial agents from a chemical and biochemical perspective.

Ohio University – Chemistry 3070, Organic Chemistry. ~140 students, spring/fall quarters, final quarter of a two semester organic chemistry sequence.

At Ohio State University I taught the following courses in the professional pharmacy program and in the graduate medicinal chemistry program.

Ohio State University - Pharmacy 441, Medicinal Chemistry II. 150-120 undergraduate professional pharmacy students, Winter quarter. The chemical and biological principles of drugs affecting the peripheral and central nervous system.

Ohio State University - Pharmacy 835, Advanced Medicinal Chemistry - Synthesis and Properties of Heterocycles. 12-18 graduate students, Autumn quarter. Methods for the synthesis of heterocycles, their properties and medicinal chemical significance.

Ohio State University - Pharmacy 839, Problem Solving in Natural Products Chemistry. 6-10 graduate students, Autumn, Winter and Spring quarters.

Ohio State University - Pharmacy 735, Drug Discovery and Design. 10-15 graduate students, spring quarter. An introduction to the study of medicinal chemistry focusing on drug design, drug-macromolecule interactions and drug metabolism.

Ohio State University - Nominated for the Miriam Balshone Teaching Award in 1998, 1997 and 1996.

Professional Service

Grant reviews

Ad hoc panel reviewer for the National Institutes of Health: 2002-2020 – 1-6 study sections per year.

Grant Review Panel for the US – Egypt Joint Board on Scientific and Technological Cooperation

Grant Review Panel for the Romanian Executive Agency for Higher Education, Research, Development and Innovation Funding.

Ad hoc grant review for Armenian-U.S. Bilateral Grants Program

Ad hoc grant reviews for the American Chemical Society – Petroleum Research Fund (1 – 2 per year)

Ad hoc grant reviews for the Research Corporation

Ad hoc grant reviews for National Science Foundation (1 – 2 per year)

Manuscript reviews for the following journals: (12-15 per year)

Organic Letters, Journal of Organic Chemistry, Journal of the American Chemical Society, Tetrahedron Letters, Tetrahedron, Bioorganic & Medicinal Chemistry Letters, Accounts of Chemical Research, Organic Preparations and Procedures, Chemical Reviews, Chemical Communications, Synthesis, SynLett

Departmental/University Service

Department of Chemistry & Biochemistry committees

Graduate Recruitment Committee

Member – August 2006 – October 2008, August 2000 – August 2002

- Responsible for evaluation and recommendation of new graduate students for admission into the chemistry graduate program.

Chair – August 2002 – August 2006

- Directed recruitment and admission of new graduate students.
- Redesigned and updated the chemistry graduate program booklet.
- Obtained funding for recruitment trips to China for the recruitment of graduate students.

WWW and Computer Committee

Chair – August 2002 – August 2009

- Directed a redesign and reorganization of the chemistry department website.
- Direct IT personnel on maintenance and upgrades to the website.

Instrument Committee

Chair – August 2004 – 2006

- Advocated and secured funding from university administration to upgrade existing routine NMR spectrometer.

- Wrote two NSF instrumentation grants (2003 and 2004).

Space Committee

Chair – August 2007 – August 2009

- Advise the department chair on space allocation.

Organic Search Committee

Chair July 2005 – May 2006

- Successfully directed departmental efforts to hire a new organic chemistry faculty member.

Ohio University committees

Graduate Council

Chair: September 2015 – May 2018

Member: September 2012 – August 2015

- The Council initiates, reviews, and recommends university-wide policy and new directions for graduate education.

Translational Biomedicine PhD Program Steering Committee

Member: July 2014 - current

Bioengineering Steering Committee

Member: July 2009 – current

- Formulate plans and submit funding proposals to the Russ College of Engineering.

Konneker Medal Selection Committee

Member: December 2013, 2014

Technology Transfer Office Associate Director Search Committee

Member: June 2013 – June 2016

- Evaluate and interview applicants for the Director of the Technology Transfer Office.

Translational Biomedicine PhD Program Development Committee

Chair – October 2011 – September 2012

- Directing a multi-college committee in the preparation of a new PhD degree program in translation biomedicine

Robert and Rene Glidden Visiting Professorship Committee

Chair: 2008

Member: 2006 - 2008

- Led committee of eight to evaluate and recommend applicants for the Robert and Rene Glidden Visiting Professorship.

College of Arts & Sciences, Faculty Development Committee

Chair: September 2009 – 2010

Member: September 2006 – 2009

- Evaluate and recommend applicants for Faculty Fellowship Leaves and Faculty Development Awards.

Engineering Faculty Search Committee

Member: September 2006 – April 2007

- Evaluate and interview applicants for the new Biomedical Engineering position.

College of Arts & Sciences Promotion and Tenure Committee

Member: 2005, 2006, 2007, 2010, 2011, 2012, 2013

- Evaluate promotion and tenure dossiers for the College of Arts and Sciences.

Technology Transfer Office Director Search Committee

Member: September 2009 – January 2010

- Evaluate and interview applicants for the Director of the Technology Transfer Office.

EDUCATION

Ph.D. in Medicinal Chemistry

University of Michigan, Ann Arbor, Michigan

September 1984 - December 1990

Research Advisor: Dr. William H. Pearson

Dissertation: *The Total Synthesis of (-)-Slaframine and the Synthesis of Triazole Analogues of the Dehydropyrrolizidine Alkaloids.*

M.S. in Organic Chemistry

University of Nebraska, Lincoln, Nebraska

September 1978 - August 1981

Research Advisor: Dr. Raymond L. Funk

Thesis: *The Total Synthesis of Grandisol and Related Studies.*

B.S. in Chemistry

Iowa State University, Ames, Iowa

September 1974 - May 1978

PUBLICATIONS & PATENTS

1. 4-(1,2,5,6-Tetrahydro-1-Alkyl-3-Pyridinyl)-2-Thiazolamines and 4-(Hexahydro-1-Alkyl-3-Pyridinyl)-2-Thiazolamines Having Anti-Psychotic Activity. J. C. Jaen, L. D. Wise, H. Tecle, S. C. Bergmeier **U.S. Patent 4,650,805** Mar. 17, 1987.
2. O-Substituted Tetrahydropyridine Oxime Cholinergic Agents. S. C. Bergmeier, D. A. Downs, W. H. Moos, D. W. Moreland, H. Tecle **U.S. Patent 4,710,508** Dec. 1, 1987.
3. 4-(1,2,5,6-Tetrahydro-1-Alkyl-3-Pyridinyl)-2-Thiazolamines and 4-(Hexahydro-1-Alkyl-3-Pyridinyl)-2-Thiazolamines. J. C. Jaen, L. D. Wise, H. Tecle, S. C. Bergmeier **U.S. Patent 4,739,067** Apr. 19, 1988.

4. O-Substituted Tetrahydropyridine Oxime Cholinergic Agents. S. C. Bergmeier, D. A. Downs, W. H. Moos, D. W. Moreland, H. Tecle **U.S. Patent 4,786,648** Nov. 22, 1988.
5. 4-(N-Substituted Amino)-2-Butynyl-1-Carbamates and Thiocarbamates and Derivatives Thereof as Centrally Acting Muscarinic Agents. S. C. Bergmeier, J. A. Kester, W. A. Moos, H. Tecle, A. J. Thomas **U.S. Patent 4,996,201** Feb. 2, 1991.
6. Alkyl Substituted 3-PPP Derivatives. Synthesis and Biological Investigation. H. Tecle, S. C. Bergmeier, L. D. Wise, H. Hershenson, L. Coughenour, T. G. Heffner, *J. Heterocyclic Chem.* **1989**, 26, 1125-1128.
7. 4-(1,2,5,6-Tetrahydro-1-alkyl-3-pyridinyl)-2-thiazolamines: A Novel Class of Compounds with Central Dopamine Agonist Properties. J. C. Jaen, L. D. Wise, B. Caprathe, H. Tecle, S. C. Bergmeier, C. C. Humblet, T. G. Heffner, L. T. Meltzer, T. A. Pugsley, *J. Med. Chem.* **1990**, 33, 311-317.
8. The Synthesis of Triazole Analogues of Antitumor Dehydropyrrolizidine Alkaloids. W. H. Pearson, S. C. Bergmeier, & J. A. Chytra, *Synthesis* **1990**, 156-159.
9. Synthesis of Pyrrolizidines and Indolizidines by the Intramolecular Cycloaddition of Azides with Electron-Rich 1,3-Dienes. W. H. Pearson, S. C. Bergmeier, S. Degan, K. - C. Lin, Y. -F. Poon, J. M. Schkeryantz, & J. P. Williams, *J. Org. Chem.* **1990**, 55, 5719-5738.
10. Synthesis of Indolizidines by the 1,3-Dipolar Cycloaddition of Azides with Methylene-Cyclopropanes Followed by Cyclopropylimine Rearrangement. P. C. Heidt, S. C. Bergmeier, & W. H. Pearson, *Tetrahedron Lett.* **1990**, 31, 5441-5444.
11. A Synthesis of (-)-Slaframine and (-)-1,8a-Diepislaframine. W. H. Pearson & S. C. Bergmeier, *J. Org. Chem.* **1991**, 56, 1976-1978.
12. Synthesis of (-)-Slaframine and Related Indolizidines. W. H. Pearson, S. C. Bergmeier, & J. P. Williams, *J. Org. Chem.* **1992**, 57, 3977-3987.
13. Cholinergic agents. Effect of Methyl Substitution on Muscarinic Acetylcholine Receptor Binding in a Series of Arecoline Derivatives. W. H. Moos, S. C. Bergmeier, L. L. Coughenour, R. E. Davis, F. M. Hershenson, J. A. Kester, J. S. McKee, J. G. Marriot, R. D. Schwarz, H. Tecle, A. J. Thomas, *J. Pharm. Sci.* **1992**, 81, 1015-1019.
14. Chirospecific Synthesis of (1S,3R)-1-Amino-3-hydroxymethylcyclopentane, A Precursor for Carbocyclic Nucleoside Synthesis. Dieckmann Cyclization with an α -Amino Acid. S. C. Bergmeier, A. A. Cobas, H. Rapoport, *J. Org. Chem.* **1993**, 58, 2369-2376.
15. Chirospecific Synthesis of (1S,3R)-1-Amino-3-hydroxymethylcyclopentane, A Precursor for Carbocyclic Nucleoside Synthesis. Intramolecular Aziridine Cyclizations. S. C. Bergmeier, W. K. Lee, & H. Rapoport, *J. Org. Chem.* **1993**, 58, 5019-5022.
16. Selective Removal of an N-BOC Protecting Group in the Presence of a *tert*-Butyl Ester and Other Acid-Sensitive Groups. F. A. Gibson, S. C. Bergmeier, & H. Rapoport, *J. Org. Chem.* **1994**, 59, 3216-3218.
17. Synthesis of (1R,3R,5S)-1-Amino-3-hydroxymethyl-bicyclo[3.1.0]hexane as a Precursor for the Synthesis of Carbocyclic Nucleosides. H. S. Chang, S. C. Bergmeier, J. A. Frick, A. Bathe, & H. Rapoport, *J. Org. Chem.* **1994**, 59, 5336-5342.
18. Synthesis of γ -Amino Olefins. An Intramolecular Aziridine - Allylsilane Reaction . S. C. Bergmeier & P. P. Seth, *Tetrahedron Lett.* **1995**, 36, 3793-3796.

19. A Directed Amidohalogenation Reaction. An Unusual Reaction of Azidoformates. S. C. Bergmeier & D. M. Stanchina, *Tetrahedron Lett.* **1995**, 36, 4533-4536.
20. Aziridines and Azirines: Monocyclic. W. H. Pearson, B. W. Liam, & S. C. Bergmeier In *Comprehensive Heterocyclic Chemistry II*; Padwa, A. Ed.; Pergamon, Oxford: Volume 1, 1996.
21. Formation of Scalemic Aziridines via the Nucleophilic Opening of Aziridines. S. C. Bergmeier & P. P. Seth, *J. Org. Chem.* **1997**, 62, 2671-2674.
22. Synthesis of Vicinal Aminoalcohols via a Tandem Acylnitrene Aziridination - Aziridine Ring Opening. S. C. Bergmeier & D. M. Stanchina, *J. Org. Chem.* **1997**, 62, 4449-4456.
23. Synthesis of Oligo(5-Aminopentanoic acid)-Nucleobases (APN): Potential Antisense Agents. S. C. Bergmeier & S. L. Fundy, *Bioorg Med. Chem. Lett.* **1997**, 7, 3135-3138.
24. Synthesis And Antiviral Activity Of Novel Aza-Acyclonucleosides. S. C. Bergmeier, S. L. Fundy & J. Drach, *Nucleosides & Nucleotides* **1999**, 18, 227-238.
25. An Acylnitrene Route to Vicinal Amino Alcohols. Application to the Synthesis of (-)-Bestatin and Analogues. S. C. Bergmeier & D. M. Stanchina, *J. Org. Chem.* **1999**, 64, 2852-2859.
26. An Aziridine-Allylsilane Mediated Total Synthesis of (-)-Yohimbane. S. C. Bergmeier & P. P. Seth, *J. Org. Chem.* **1999**, 64, 3237-3243.
27. Synthesis of Bicyclic Proline Analogs Using a Formal [3+2] Intramolecular Aziridine-Allylsilane Cycloaddition Reaction. S. C. Bergmeier, S. L. Fundy & P. P. Seth, *Tetrahedron* **1999**, 55, 8025-8038.
28. Deprotection of *N*-Tosyl Aziridines with Sodium Naphthalenide. S. C. Bergmeier & P. P. Seth, *Tetrahedron Lett.* **1999**, 40, 6181-6184.
29. Ring E Analogs of Methyllycaconitine as Nicotinic Antagonists. S. C. Bergmeier, D. J. Lapinsky, R. B. Free & D. B. McKay, *Bioorg. Med. Chem. Lett.* **1999**, 9, 2263-2266.
30. The Synthesis of Vicinal Amino Alcohols. S. C. Bergmeier, *Tetrahedron* **2000**, 56, 2561-2576. (Invited review)
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33. Synthesis of Monosubstituted Succinic Acids from *tert*-Butylsuccinate. S. C. Bergmeier & K. A. Ismail, *Synthesis* **2000**, 1369-1371.
34. A Suzuki Cross-Coupling Route to Substituted Aziridines. D. J. Lapinsky & S. C. Bergmeier, *Tetrahedron Lett.* **2001**, 42, 8583-8586.
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36. Structure-Activity Studies with Ring E Analogues of Methyllycaconitine on Bovine Adrenal $\alpha 3\beta 4^*$ Nicotinic Receptors. D. L. Bryant, R. B. Free, S. M. Thomasy, D. J. Lapinsky, K. A. Ismail, S. B. McKay, S. C. Bergmeier & D. B. McKay, *Neurosci. Res.* **2002**, 42, 57-63.

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39. A Method for the Parallel Synthesis of Multiply Substituted Oxazolidinones. S. J. Katz, & S. C. Bergmeier, *J. Comb. Chem.* **2002**, 4, 162-166.
40. The Effects of Methyllaconitine (MLA) and Related Analogues on Bovine Adrenal $\alpha 3\beta 4^*$ Nicotinic Acetylcholine Receptors. D. L. Bryant, R. B. Free, S. M. Thomasy, D. J. Lapinsky, K. A. Ismail, K. M. Arason, S. C. Bergmeier & D. B. McKay. *Ann. N. Y. Acad. Sci.* **2002**, 971, 139-141.
41. Structure-Activity Studies with Ring E Analogues of Methyllaconitine. Synthesis and Evaluation of Enantiopure Isomers of a Selective Antagonist at the $\alpha 3$ Nicotinic Receptor. K. A. Ismail & S. C. Bergmeier, *Eur. J. Med. Chem.* **2002**, 37, 469-474.
42. Aziridine-Allylsilane Cyclizations. Formation of Azabicyclo [n.2.1] Ring Systems. D. J. Lapinsky & S. C. Bergmeier, *Tetrahedron* **2002**, 58, 7109-7117. (Invited article for a Symposia in print, Application of strained heterocycles as reactive intermediates in organic synthesis).
43. Intramolecular Cyclization Reactions of Aziridines with π -Nucleophiles. S. C. Bergmeier, S. J. Katz, J. Huang, H. McPherson, P. Donohugh & D. D. Reed, *Tetrahedron Lett.* **2004**, 45, 5011-5014
44. Structure Activity Studies of Ring E Analogues of Methyllaconitine. II. Synthesis of Antagonists to the $\alpha 3\beta 4^*$ Nicotinic Acetylcholine Receptors Through Modifications to the Ester. S. C. Bergmeier, K. A. Ismail, K. M. Arason, S. McKay, D. L. Bryant & D. B. McKay, *Bioorg. Med. Chem. Lett.* **2004**, 14, 3739-3742.
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46. Resolution of Methyl Nonactate by *Rhodococcus erythropolis* under Aerobic and Anaerobic Conditions. J. Nikodinovic, J. M. Dinges, S. C. Bergmeier, M. C. McMills, D. L. Wright, & N. D. Priestley, *Org. Lett.* **2006**, 8, 443-445.
47. Structure Activity Studies of Oxazolidinone Analogs as RNA-Binding Agents. J. Means, S. J. Katz, R. Anupam, A. Nayek, J. V. Hines, & S. C. Bergmeier, *Bioorg. Med. Chem. Lett.* **2006**, 16, 3600-3604.
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52. Analogs Of Methyllaconitine As Novel Noncompetitive Inhibitors of Nicotinic Receptors: Pharmacological Characterization, Computation Modeling, And Pharmacophore Development. D. B. McKay, C. Chang, T. Gonzalez, S. B. McKay, R. El-Hajj, D. L. Bryant, P. W. Swaan, K. M. Arason, A. B. Pulipaka, C. M. Orac, & S. C. Bergmeier, *Mol. Pharmacol.* **2007**, 71, 1288-1297.
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56. Synthesis of hexahydro-1H-benzo[c]chromen-1-amines via the intramolecular ring opening reactions of aziridines by π -nucleophiles. A. B. Pulipaka & S. C. Bergmeier, *Synthesis* **2008**, 1320-1329.
57. A Knoevenagel Condensation Route for the Synthesis of a Highly Substituted cis-Decahydroquinoline. J. Huang & S. C. Bergmeier, *Tetrahedron* **2008**, 64, 6434-6439.
58. 4,5-Disubstituted Oxazolidinones: High Affinity Molecular Effectors of RNA Function. R. Anupam, S. C. Bergmeier, N. J. Green, F. J. Grundy, T. M. Henkin, J. A. Means, A. Nayek & J. V. Hines, *Bioorg. Med. Chem. Lett.* **2008**, 18, 3541-3544.
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95. Factors that influence T box riboswitch efficacy and tRNA affinity. C. Zeng, S. Zhou, S.C. Bergmeier, J.V. Hines, *Bioorg. Med. Chem.* **2015**, 23, 5702.
96. A synthesis of hexahydro *H*-oxazolo[3,4-*a*]pyrazin-3-ones from fused aziridines. F. Fang, I. Maciagiewicz, S.C. Bergmeier, *Heterocycles* **2016**, 93, 422-439.
97. Development of a method for the synthesis of 4-aryl functionalized 2-azabicyclo[3.2.1]octanes. Ian Armstrong, S. C. Bergmeier, *Synthesis*, **2017**, 2733-2742
98. Phenylmethimazole and a thiazole derivative of phenylmethimazole inhibit IL-6 expression by triple negative breast cancer cells. N.S. Mahboubah, J.D. O'Brien, Z.J. Champa, S.P. Deosarkar, O.L. Lanier, C. Qi, M.M. Burdick, F.L. Schwarz, S.C. Bergmeier, K.D. McCall, D.J. Goetz. *Eur. J. Pharmacol.* **2017**, 803, 130-137.
99. Routes to N-glycinamide oxazolidinone derivatives: The reaction of 4-trityloxymethyl-3-oxa-1-azabicyclo[3.1.0]hexan-2-one with active halides. Z. Zheng & S.C. Bergmeier, *Arkivoc*, **2019**, DOI: <https://doi.org/10.24820/ark.5550190.p010.812>
100. Identification of a Novel Selective and Potent Inhibitor of Glycogen Synthase Kinase-3. N.S. Mahboubah, P.M. Bhatt Pooja, D. Ghazanfari, M.C. Courreges, C. Cuckler, C.M. Orac, M.C. McMills, F.L. Schwartz, S.P. Deosarkar, S.C. Bergmeier, K.D. McCall, D.J. Goetz, *Am. J. Physiol.: Cell Physiol.* **2019**, 1522-1563
101. Isosteres of ester derived glucose uptake inhibitors. D.A. Roberts, L. Wang, W. Zhang, Y. Liu, P. Shriwas, Y. Qian, X. Chen, S.C. Bergmeier, *Bioorg. Med. Chem. Lett.* **2020**, 30, 127406
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103. Modulation of LPS-induced inflammatory cytokine production by a novel glycogen synthase kinase-3 inhibitor. M.S. Noori, M.C. Courreges, S.C. Bergmeier, K.D. McCall, D.J. Goetz, *Eur. J. Pharmacol.* **2020**, 883, 17334
104. A novel GSK-3 inhibitor binds to GSK-3 β via a reversible, time and Cys-199-dependent mechanism. Ghazanfari, D.; Noori, M.S.; Bergmeier, S.C.; Hines, J.V.; McCall, K.D.; Goetz, D.J. *Bioorg. Med. Chem.* **2021**, 40, 116179
105. A small-molecule pan-class I glucose transporter inhibitor reduces cancer cell proliferation in vitro and tumor growth in vivo by targeting glucose-based metabolism. P. Shriwas, D. Roberts, Y. Li, L. Wang, Y. Qian, S. Bergmeier, J. Hines, S. Adhicary, C. Nielsen, X. Chen. *Cancer & Metabolism*, **2021**, 9, 14, 1-14

PRESENTATIONS

34th National Organic Symposium, June 11-15, 1995. Poster #91; *Intramolecular Aziridine-Allylsilane Reactions*.

34th National Organic Symposium, June 11-15, 1995. Poster #90; *Amidohalogenation Reactions of Azidoformates*.

Ohio State University, Columbus, Ohio, Department of Chemistry, May 1, 1997. Organic Division, Invited seminar; *Aziridines in Drug Design and Synthesis*.

35th National Organic Symposium, San Antonio, Texas, June 22-26, 1997. Poster #T163; *Acynitrene Mediated Synthesis of (-)-Bestatin*.

Gordon Research Conference on Heterocyclic Compounds, Newport, Rhode Island, June 29-July 4 1997. Poster; *Synthesis and Reactions of Bicyclic Aziridines*.

Tularik, Inc., South San Francisco, California, Sept. 19, 1997. Invited seminar; *Acynitrenes for the Synthesis of Amino Alcohols*.

Corvas, San Diego, California, Nov. 18, 1997. Invited seminar; *Acynitrenes for the Synthesis of Vicinal Amino Alcohols*.

MitoKor Inc., San Diego, California, Jan. 9, 1998. Invited seminar; *Acynitrenes for the Synthesis of Vicinal Amino Alcohols*.

Combichem Inc., San Diego, California, March 27, 1998. Invited seminar; *Aziridines in Organic Synthesis*.

Midwest Regional AAPS meeting, Chicago, Illinois., May 18, 1998. Invited seminar; *Acynitrenes for the Synthesis of Amino Alcohols*.

Gordon Research Conference on Heterocyclic Compounds, Newport, Rhode Island, June 28-July 3, 1998. Invited seminar; *Aziridine-Allylsilane Cyclizations. Problems, Solutions and Applications*.

Ohio University, Athens, Ohio, Department of Chemistry. Oct. 23, 1998. Invited seminar; *Aziridine-Allylsilane Cyclizations. Problems, Solutions and Applications*.

University of Iowa, Iowa City, Iowa, Department of Chemistry. Feb. 5, 1999. Invited seminar; *Aziridine-Allylsilane Cyclizations. Problems, Solutions and Applications*.

36th National Organic Symposium, Madison, Wisconsin, June 13-17, 1999. Poster #87; *Synthesis of Bicyclic Proline Analogs Using a Formal [3+2] Intramolecular Aziridine-Allylsilane Cycloaddition Reaction*.

36th National Organic Symposium, Madison, Wisconsin, June 13-17, 1999. Poster #148; *Ring E Analogs of Methyllaconitine as Nicotinic Antagonists*.

Gordon Research Conference on Heterocyclic Compounds, Newport, Rhode Island, June 27-July 1 1999. Poster; *Ring E Analogs of Methyllaconitine as Nicotinic Antagonists*.

Eastern Michigan University, Ypsilanti, Michigan, Department of Chemistry, Oct. 18, 1999. Invited seminar: *Aziridines, Allylsilanes and Nicotinic Antagonists*.

Society for Neuroscience Annual Meeting, Miami Beach, Florida, Oct. 23 – Oct. 28, 1999. Poster #497.3: *Ring E Analogs of Methyllycaconitine as Nicotinic Antagonists*.

Ohio State University, Columbus, Ohio, Department of Pharmacology, Feb 1, 2000. Invited seminar: *Aziridines, Allylsilanes and Nicotinic Antagonists*.

University of Montana, Missoula, Montana, Department of Chemistry, Feb. 7, 2000. Invited seminar: *Aziridines, Allylsilanes and Nicotinic Antagonists*.

219th American Chemical Society National Meeting, San Francisco, California, March 26 - 30, 2000. Paper #319; *Ring E Analogs of Methyllycaconitine as Nicotinic Antagonists*.

Michigan Technological University, Houghton, Michigan, Department of Chemistry, April 7, 2000. Invited seminar: *Aziridines, Allylsilanes and Nicotinic Antagonists*.

Upper Ohio Valley Section, American Chemical Society, October 19, 2000. Invited seminar: *Aziridines, Allylsilanes and Nicotinic Antagonists*.

University of Florida, Gainesville, Florida, Department of Chemistry, November 16, 2000. Invited seminar: *Aziridines, Allylsilanes and Nicotinic Antagonists*.

University of Memphis, Memphis, Tennessee, Department of Chemistry, February 23, 2001. Invited seminar: *Aziridines, Allylsilanes and Nicotinic Antagonists*.

Miami University, Oxford, Ohio, Department of Chemistry, April 12, 2001. Invited seminar: *Aziridine – Allylsilane Cyclizations, Applications and Future Directions*.

37th National Organic Symposium, Bozeman, Montana, June 10-14, 2001. Poster #40; *Structure – Activity Studies with Ring E Analogues of Methyllycaconitine*.

37th National Organic Symposium, Bozeman, Montana, June 10-14, 2001. Poster #115; *Synthesis of Azabicyclo[x.2.1]-Systems Using a Intramolecular Aziridine-Allylsilane Cyclization Reaction*.

Gordon Research Conference on Heterocyclic Compounds, Newport, Rhode Island, July 8-July 13 2001. Poster; *Synthesis of Aza-bicyclo[n.2.1]-Ring Systems*.

Gordon Research Conference on Combinatorial Chemistry, Tilton, New Hampshire, July 15-July 20 2001. Poster; *Parallel Synthesis of Multiply Substituted 2-Oxazolidinones*.

Michigan State University, East Lansing, Michigan, Department of Chemistry, March 14, 2002. Invited seminar: *Aziridines in Diversity-Oriented Synthesis*.

Wayne State University, Detroit, Michigan, Department of Chemistry, April 9, 2002. Invited seminar: *Aziridines in Diversity-Oriented Synthesis*.

University of Michigan, Ann Arbor, Michigan, Department of Chemistry, April 10, 2002. Invited seminar: *Aziridines in Diversity-Oriented Synthesis*.

Gordon Research Conference on Heterocyclic Compounds, Newport, Rhode Island, July 7-July 12 2002. Poster; *Intramolecular Friedel-Crafts Reactions of Aziridines*.

University of Nebraska, Lincoln, Nebraska, Department of Chemistry, October 1, 2002. Invited seminar: *Aziridines in Organic Synthesis*.

University of Kansas, Lawrence, Kansas, Department of Medicinal Chemistry, October 3, 2002. Invited seminar: *Aziridines in Organic Synthesis*.

University of Toledo, Toledo, Ohio, Department of Medicinal Chemistry, October 17, 2002. Invited seminar: *Aziridines, Combinatorial Chemistry and Nicotinic Antagonists*.

University at Albany, Albany, New York, Department of Chemistry, September 23, 2003.
Invited seminar : *Aziridines, Allylsilanes and Nicotinic Antagonists*.

University of Louisville, Louisville, Kentucky, Department of Chemistry, January 13, 2004.
Invited seminar: *Aziridines, Allylsilanes and Nicotinic Antagonists*.

University at Brockport, Brockport, New York, Department of Chemistry, February 20, 2004.
Invited seminar: *Aziridines, Allylsilanes and Nicotinic Antagonists*.

Canisius College, Buffalo, New York, Department of Chemistry, February 20, 2004. Invited seminar: *Aziridines, Allylsilanes and Nicotinic Antagonists*.

St. Vincent's College, Pennsylvania, Department of Chemistry, March 12, 2004. Invited seminar: *Aziridines, Allylsilanes and Nicotinic Antagonists*.

Ohio Valley Organic Chemistry Symposium, Dayton, Ohio, May 14-15, 2004. Invited seminar: *Aziridines in Diversity – Oriented Synthesis*.

Universistät Leipzig, Fakultät für Chemie und Mineralogie, Institut für Organische Chemie, Universität Leipzig, Leipzig, Germany, July 6, 2004. Invited seminar: *Aziridines in Diversity – Oriented Synthesis*.

Gordon Research Conference on Natural Products, Tilton, New Hampshire, July 25 –30, 2004. Poster: *Chemistry and Medicinal Chemistry of the Norditerpenoid Alkaloid Methyllycaconitine*.

228th American Chemical Society National Meeting, Philadelphia, Pennsylvania, August 22 – 26, 2004. Poster #85: *Structure Activity Studies of Ring E Analogues of Methyllycaconitine. Synthesis of Antagonists to the $\alpha 3\beta 4^*$ Nicotinic Acetylcholine Receptors*

228th American Chemical Society National Meeting, Philadelphia, Pennsylvania, August 22 – 26, 2004. Poster #84: *Structure Activity Studies of Multiple Ring Analogues of Methyllycaconitine. Synthesis of Antagonists to the Nicotinic Acetylcholine Receptors*.

20th International Congress of Heterocyclic Chemistry, Palermo, Italy, July 31 – August 5, 2005. Invited presentation: *Synthesis and Biological Activity of Ring E/F and Ring E/B Analogues of Methyllycaconitine*.

Brock University, St. Catherines, Ontario, Canada, October 7, 2005. Invited seminar: *Alkaloid Analogs as Nicotinic Antagonists*.

Gordon Research Conference on Bioorganic Chemistry, Oxford, England, July 30 – August 5, 2006. Poster: *Ring Opening Reaction of 3-Oxa-1-azabicyclo[3.1.0]-hexan-2-ones; A Facile Synthesis of Aminomethyl Oxazolidinones*.

232nd American Chemical Society National Meeting, San Francisco, California, September 10 – September 14, 2006. Poster 538: *Synthesis and Evaluation of Ring EB Analogs of Methyllycaconitine*.

232nd American Chemical Society National Meeting, San Francisco, California, September 10 – September 14, 2006. Poster 541: *Methyl Nonactate as a Starting Scaffold for the Parallel Synthesis of Compound Libraries*.

38th Central Regional ACS meeting, Covington KY, May 19 – May 23 2007. *Microwave accelerated reactions in parallel synthesis*. Invited presentation – Symposium on Microwaves in Synthesis.

40th National Organic Symposium, June 3 - 7, 2007, Duke University, *Intramolecular Cyclization Reactions of Aziridines with π -Nucleophiles*, Poster #C78.

40th National Organic Symposium, June 3 - 7, 2007, Duke University, *The Lewis acid promoted [3+2] cycloaddition reaction of cyclohexenylsilanes with electron-deficient double bonds*. Poster #C65.

Universität Leipzig, Institute für Organische Chemie, December 3, 2007. Invited seminar: *Aziridine-based approaches to alkaloids and alkaloid analogs*.

University of Connecticut, Department of Pharmaceutical Sciences, June 5, 2008. Invited seminar: *The search for novel antimicrobial agents. A serendipitous marriage of organic chemistry and structural biology*.

31st National Medicinal Chemistry Symposium, June 15 – 19, 2008, University of Pittsburgh, Poster #116: *A library of 1,4-disubstituted 1,2,3-triazoles analogs of the oxazolidinone antibacterial/RNA-binding agents*.

13th Latest Trends in Organic Synthesis, August 13 – 16, 2008, Brock University, St. Catharines, Ontario. Poster: *Intramolecular reactions of aziridines with π -nucleophiles*.

Gordon Research Conference on Combinatorial Chemistry, September 1 – 5, 2008, Magdalen College, Oxford University, Oxford, England. Poster: *Natural product-based parallel synthesis*.

EMBL Conference on Chemical Biology, October 8 – 11, 2008, European Molecular Biology Laboratories, Heidelberg, Germany. Poster: *Stereoselectivity in the binding of small molecules to T-box RNA*.

22nd International Congress on Heterocyclic Chemistry, August 1 – 7, 2009, St. John's Newfoundland, Canada, Invited Presentation: *3-oxa-1-azabicyclo[3.1.0]-hexan-2-one as a convenient starting scaffold for the synthesis of imidazolinones, substituted piperazines and piperazino[1,2-e]triazoles*.

Duquesne University, Department of Chemistry & Biochemistry, February 1, 2010, Invited presentation: *The development of new reactions involving aziridines*.

239th American Chemical Society National Meeting, March 21-25, 2010, San Francisco CA. Presentation: *3-oxa-1-azabicyclo[3.1.0]-hexan-2-one as a convenient starting scaffold for the synthesis of imidazolidinones and substituted piperazines*

239th American Chemical Society National Meeting, March 21-25, 2010, San Francisco CA. Poster: *Inhibitors of basal glucose transport as anticancer agents*, MEDI 363.

239th American Chemical Society National Meeting, March 21-25, 2010, San Francisco CA. Poster: *Fluorescence anisotropy screening for inhibitors of tRNA-T Box antiterminator RNA riboswitch interaction*, MEDI 423.

14th Symposium on the Latest Trends in Organic Synthesis, August 11 – 14, 2010, Brock University, St. Catharines, Ontario, Canada, Invited Presentation: *Reactions of aziridines as a route to chemical diversity*.

Science Café – Ohio University, January 26, 2011, Invited Presentation: *Chemistry, the class you love to hate and drug discovery*.

Old Dominion University, Department of Chemistry, Invited presentation, Feb 23, 2011, *Reactions of aziridines as a route to chemical diversity*.

Gordon Research Conference on Heterocyclic Chemistry, Salve Regina University, Newport, RI, June 26 – June 30, 2011, Poster: *Fused-ring aziridines for the synthesis of aziridinyl ureas*.

Wichita State University, Department of Chemistry, Invited presentation, Sept 21, 2011, *Reactions of aziridines as a route to chemical diversity*.

243rd American Chemical Society National Meeting, March 25-29, 2012, San Diego, CA. Poster: *Synthesis and utility of novel peptidomimetics containing hydroxyethyl isostere and imodazolidinone*, MEDI 112.

Ohio University Chapter of Sigma Xi, New methods for small molecule synthesis. Applications to the discovery of new therapeutics. April 4, 2013 (invited presentation)

245th National Meeting of the American Chemical Society, New Orleans, LA, April 7 – 11, 2013, Founding and evolution of a startup pharmaceutical company (final paper number: 23) Invited Presentation to the True Stories of Success Session, S. C. Bergmeier, M. C. McMills, N. D. Priestley, D. L. Wright

245th National Meeting of the American Chemical Society, New Orleans, LA, April 7 – 11, 2013, Novel isosteviol derivatives as potential anticancer agents, Poster # MEDI-80, R. Laha, A. Malki, & S. C. Bergmeier

245th National Meeting of the American Chemical Society, New Orleans, LA, April 7 – 11, 2013, Synthesis of N-acyl aziridine containing peptidomimetics, Presentation # MEDI-274, G. M. Wells & S. C. Bergmeier

34th National Medicinal Chemistry Symposium, Charleston, SC, May 18 – 21, 2014, RNA Drug Discovery: Extension and Conformational Restriction Enhance Modulation of T Box Riboswitch Function, Chunxi Zeng, Ian Armstrong, Jia Liu, Fang Fang, Jennifer V. Hines, Stephen C. Bergmeier

34th National Medicinal Chemistry Symposium, Charleston, SC, May 18 – 21, 2014, Small Molecule Inhibitors of Glucose Uptake as Anticancer Agents, Dennis A. Roberts, Weihe Zhang, Yi Liu, Yanrong Qian, Xiaozhuo Chen, Stephen C. Bergmeier

35th National Medicinal Chemistry Symposium, Chicago, IL, June 26-29, 2016. Inhibitors of glucose transport as anticancer agents. Emma Kessler, Johannes Diesel, Yanrong Qian, Pratik Shriwas, Maximillian Munzer, Jennifer V. Hines, Xiaozhuo Chen, Stephen C. Bergmeier

John Carroll University, Department of Chemistry, Cleveland, OH, October 12, 2016. Inhibitors of Glucose Uptake - A New Cancer Therapy. Weihe Zhang, Dennis Roberts, Emma Kessler, Johannes Diesel, Yanrong Qian, Pratik Shriwas, Maximillian Munzer, Liyi Wang, Jennifer V. Hines, Xiaozhuo Chen, Stephen C. Bergmeier

Hong Kong Baptist University, Department of Chemistry, Hong Kong, China, December 5, 2016. Inhibitors of Glucose Uptake - A New Cancer Therapy. Weihe Zhang, Dennis Roberts, Emma Kessler, Johannes Diesel, Yanrong Qian, Pratik Shriwas, Maximillian Munzer, Liyi Wang, Jennifer V. Hines, Xiaozhuo Chen, Stephen C. Bergmeier

Shandong Normal University, Department of Chemistry, Jinan, China, December 8, 2016. Inhibitors of Glucose Uptake - A New Cancer Therapy. Weihe Zhang, Dennis Roberts, Emma Kessler, Johannes Diesel, Yanrong Qian, Pratik Shriwas, Maximillian Munzer, Liyi Wang, Jennifer V. Hines, Xiaozhuo Chen, Stephen C. Bergmeier

36^h National Medicinal Chemistry Symposium, Nashville, TN, April 28 – May 2, 2018.
Fused-ring aziridines as a route to imidazolidinone based peptidomimetics. Susann H. Krake, Stephen C. Bergmeier

National Organic Symposium, Bloomington, Indiana, June 2019, Synthesis of Ether-linked Glucose Uptake Inhibitors, Liyi Wang, Emma J. Kessler, Pratik Shriwas, Jennifer V. Hines, Xiao Chen, Stephen C. Bergmeier

National Organic Symposium, Bloomington, Indiana, June 2019, The design and synthesis of RNA targeting small molecules, Eric Parsons, Benjamin J. Haines, Ian S. Armstrong, Jia L. Schopis, Jennifer V. Hines, Stephen C. Bergmeier

Tab B

CURRICULUM VITAE

Daniel Combs, MD
Assistant Professor, Tenure Eligible
Phone: 520-626-7780
Email: combs89@arizona.edu

CHRONOLOGY OF EDUCATION

08/2003-05/2007	BS in Molecular and Cellular Biology with Honors, <i>Magna Cum Laude</i> BS in Health Sciences in Physiology, <i>Magna Cum Laude</i> University of Arizona, Tucson, Arizona
08/2007-05/2011	Doctor of Medicine, Research Distinction Track University of Arizona, Tucson, Arizona
07/2011-06/2014	Pediatric Residency University of Arizona, Tucson, Arizona
08/2012-05/2013	Fellow, Leadership Education in Neurodevelopmental Disabilities (AZLEND), University of Arizona, Tucson, AZ
07/2014-06/2015	Sleep Medicine Fellowship University of Arizona, Tucson, Arizona

CHRONOLOGY OF EMPLOYMENT

07/2015 – 11/2020	Assistant Professor of Pediatrics, Clinical Scholar Track University of Arizona, Tucson, Arizona
07/2015-	Director, Pediatric Sleep Medicine Program, Banner University Medical Center-Tucson
10/2015 -	Assistant Professor of Medicine (J) University of Arizona, Tucson, Arizona
01/2016 -11/2020	Banner University Medical Group – Tucson Assistant Professor, University of Arizona, Tucson, AZ
07/2019-	Associate Program Director, Sleep Medicine Fellowship (Pediatrics)

11/2020-	Assistant Professor of Pediatrics, Tenure Eligible University of Arizona, Tucson, AZ
10/2021-	Assistant Director of Scholarly Projects, Community-based Research University of Arizona College of Medicine

Board Certification and Licenses

03/2014 -	Arizona medical license, #48789
10/2014 -	American Board of Pediatrics, Certified in General Pediatrics, # 109506
10/2015 -	American Board of Pediatrics, Board Certified in Sleep Medicine, #258

HONORS AND AWARDS

8/2006-5/2008	Solon E. Summerfield Scholar
8/2009	Kenneth Gerber Memorial Scholarship
8/2010	A C Simon Memorial Scholarship
5/2011	Excellence in Research Award- University of Arizona College of Medicine
4/2015	American Academy of Sleep Medicine Young Investigator Research Forum Travel Award
6/2015	Sleep Research Society Implementation Science Young Investigator Travel Award
10/2015	Anne Elizabeth Suratt Young Investigator Award
7/2016-6/2022	NIH/NHLBI Pediatric Research Loan Repayment Program Awardee (renewed 2018, 2020)

SERVICE/OUTREACH

National/International Outreach

7/2011-6/2015	Member, American Academy of Pediatrics
7/2014 -	Member, American Academy of Sleep Medicine
7/2014 -	Member, Sleep Research Network
10/2014-10/2015	Member, Sleep Research Society
4/2015-4/2015	Participant, American Academy of Sleep Medicine Young Investigator Forum
8/2015-6/2016	Program faculty mentor, Arizona's Science, Engineering and Mathematics Scholars (ASEMS)
12/2015	Annual conference abstract reviewer: Sleep and Development category, 2016 Associated Professional Sleep Societies
12/2016	Annual conference abstract reviewer: Sleep Disordered Breathing category, 2017 Associated Professional Sleep Societies
12/2017 -	Member, American Heart Association
01/2017 -12/2020	Member, American Sleep Medicine Foundation Career Development Award Grant Review Committee
12/2017	Annual conference abstract reviewer: Pediatrics category, 2018 Associated Professional Sleep Societies
4/2018	Ad Hoc Reviewer, University of Arizona International Research & Academic Program Development Grant Review
8/2018	Member, American Academy of Sleep Medicine Foundation Strategic Research Award Grant Review Committee
11/2018	Social media facilitator, American Heart Association Scientific Sessions 2018: Abnormal Growth in Congenital Heart Disease: Not too little, Not too much
12/2018	Annual conference abstract reviewer: Pediatrics category, 2019 Associated Professional Sleep Societies
12/2019	Annual conference abstract reviewer: Pediatrics category, 2020 Associated Professional Sleep Societies
7/2020	Member, NIH grant review committee (ZRG1 BBBP-C (55) R)

12/2020	Annual conference abstract reviewer: Sleep-Related Breathing Disorders category, 2021 Associated Professional Sleep Societies
1/2021-	Member, American Academy of Sleep Medicine Foundation Investigator-Initiated Research Grant Review Committee
11/2021	Mail Reviewer, NIH Infectious, Reproductive, Asthma and Pulmonary Conditions (IRAP) Study Section
12/2021	Annual conference abstract reviewer, 2022 Associated Professional Sleep Societies
3/2022	Member NIH grant review committee (

Ad Hoc Reviewer:

SLEEP
 Journal of Clinical Sleep Medicine
 Sleep Medicine
 Journal of Sleep Research
 Nature and Science of Sleep
 European Respiratory Journal
 Annals of the American Thoracic Society
 Paediatric Respiratory Reviews
 Respiratory Medicine
 International Journal of Chronic Obstructive Pulmonary Disease
 Journal of Intellectual and Developmental Disabilities
 Research in Developmental Disabilities
 PEDIATRICS
 Journal of Applied Physiology
 Health and Quality of Life Outcomes
 BMJ Open
 Childhood Obesity
 Journal of Clinical Medicine
 Cancer
 Future Cardiology
 International Journal of Environmental Research and Public Health
 BMC Pediatrics

Departmental Committees

7/2011-6/2014	Member, Pediatric Continuous Program Improvement Committee, University of Arizona Medical Center
07/2015-	Member, Sleep Medicine Fellowship Core Competencies Committee

- 07/2015- Member, Sleep Medicine Fellowship Program Evaluation Committee
- 9/2016-3/2017 Member, 5-Year Administrative Review Committee for Dr. Faye
Ghishan (University of Arizona Department of Pediatrics Chair
review)

College Committees

- 7/2016-7/2021 Member, University of Arizona College of Medicine Continuing
Medical Education Committee
- 7/2020- Member, University of Arizona College of Medicine Graduate
Medical Education Committee
- 7/2021-7/2022 Vice-Chair, University of Arizona College of Medicine Continuing
Medical Education Committee

University Committees

- 10/2021- Member, Institutional Review Board

PUBLICATIONS/CREATIVE ACTIVITY

Chapters in scholarly books and monographs

1. **Combs D**, Cranmer LD; Melanoma and Skin Cancer; In: *Neuropsychological Impact of Cancer and Oncology*; Springer Publishing Company; New York; 2012

Refereed Journal Articles

1. **Combs D**, Shetty S, Parthasarathy S; Advances in PAP treatment modalities for hypoventilation syndromes; *Sleep Medicine Clinics*; Sept 2014; 9(3):315-325; PMID 25346650
2. **Combs D**, Rice SA and Kopp LM; Incidence of delirium in children with cancer; *Pediatric Blood & Cancer*; Nov 2014; 61(11):2094-5; PMID 24938869
3. Buterbaugh J, Wynstra C, Provencio N, **Combs D**, Gilbert M, Parthasarathy S; Cerebrovascular Reactivity in Young Subjects with Sleep Apnea; *Sleep*; Feb 2015; 1;38(2):241-50; PMID 25409111
4. Parthasarathy S, Shetty S, **Combs D**; Mend the Mind and Mind the "MCC"; *Sleep*; Jul 1, 2015; 38(7):1001-3; PMID: 26085292

5. **Combs D**, Goodwin JL, Quan SF, Morgan WJ, Parthasarathy S; Longitudinal Differences in Sleep Duration in Hispanic and Caucasian Children; *Sleep Medicine*; Jun 29, 2015; 18:61-66; PMID: 26299467
6. **Combs D**, Goodwin JL, Quan SF, Morgan WJ, Parthasarathy S; Modified Stop-Bang Tool For Stratifying Obstructive Sleep Apnea Risk in Adolescent Children; *PLoS One*; Nov 18, 2015; 10(11):e0142242; PMID 26581088
7. **Combs D**, Shetty S, Parthasarathy S; Big-data or Slim-data: Predictive Analytics Will Rule the World; *Journal of Clinical Sleep Medicine*; 2016; 12(2):159-160; PMID 26943716
8. Yamauchi M, **Combs D**, Parthasarathy S; Adaptive Servo-Ventilation for Central Sleep Apnea in Heart Failure; *New England Journal of Medicine*; Feb 17, 2016; 374: 687-691; PMID 26886532
9. **Combs D**, Goodwin JL, Quan SF, Morgan WJ, Shetty S, Parthasarathy S; Insomnia, Health-Related Quality of Life and Health Outcomes in Children: A Seven Year Longitudinal Cohort; *Scientific Reports*; Jun 13, 2016; 6:27921; PMID 27295263
10. Grandner MA, Alfonso-Miller P, Fernandez-Mendoza J, Shetty S, Shenoy S, **Combs D**; Sleep: Important Considerations for the Prevention of Cardiovascular Disease; *Current Opinion in Cardiology*; Sep 2016; 31(5):551-6; PMID 27467177 [Review]
11. Parthasarathy S, Buysse D, Carskadon M, Jean-Louis G, Owens J, Bramoweth A, **Combs D**, Hart C, Hasler B, Honaker S, Hertenstein E, Kuna S, Kushida C, Levenson J, Murray C, Pack A, Pillai V, Pruiksma K, Seixas A, Strollo P, Thosar S, Twery M, Williams N, Stoney K; Implementation of Sleep and Circadian Science: Recommendations from the Sleep Research Society and National Institutes of Health Workshop; *Sleep*; Oct 10, 2016; 39(12):2061-2075; PMID 27748248
12. Shetty S, Fernandes A, Patel S, **Combs D**, Grandner MA, Parthasarathy S; Unanticipated Nocturnal Oxygen Requirement during Positive Pressure Therapy for Sleep Apnea and Medical Comorbidities; *Journal of Clinical Sleep Medicine*; Jan 15, 2017; 13(1):73-79; PMID 27655454
13. **Combs D**, Parthasarathy S; Machines Learning to Detect Obstructive Sleep Apnea in Children: Are We There Yet?; *American Journal of Respiratory and Critical Care Medicine*; ePub; Aug 29, 2017; PMID 28849948
14. Chin CN, **Combs D**; Glycemic improvement with improved control of sleep-disordered breathing in Prader-Willi syndrome; *Sleep and Vigilance*; Oct 12, 2017; 1:85-88

15. Quan SF, **Combs D**, Parthasarathy S; Impact of Sleep Duration and Weekend Oversleep on Body Weight and Blood Pressure in Adolescents; *Southwest Journal of Pulmonary Critical Care*; 2018; 16(1):31-41; PMID 29375933
16. Bailey O, Parthasarathy S, **Combs D**; Too Little, but Still Great?; *Journal of Clinical Sleep Medicine*; Jun 15, 2018; 14(6):907-908; PMID 29852920
17. Parthasarathy S, **Combs D**, Patel SN, Poongkunran C, Quan SF; Provider Types and Outcomes in Obstructive Sleep Apnea Case Finding and Treatment; *Annals of Internal Medicine*; Aug 7, 2018; 169(3):201-202; PMID 30083707
18. **Combs D**, Skrepnek G, Seckeler M, Barber B, Morgan WJ, Parthasarathy S; Sleep-disordered breathing is associated with increased mortality among hospitalized infants with congenital heart disease; *Journal of Clinical Sleep Medicine*; Aug 30, 2018; PMID: 30176962
19. **Combs D**, Goodwin JL, Quan SF, Morgan WJ, Hsu CH, Edgin JO, Parthasarathy S; Mother knows best? Comparing child and parent report of sleep parameters with polysomnography; *Journal of Clinical Sleep Medicine*; Jan 15, 2019; 15(1):111-117; PMID: 30621839
20. Knitter J, Bailey OF, Poongkunran C, Martinez AF, Martinez L, Kobayashi U, **Combs D**, Lane R, Zareba W, Parthasarathy S; Comparison of Physiological Performance of Four Adaptive Servo Ventilation Devices In Patients With Complex Sleep Apnea; *American Journal of Respiratory and Critical Care Medicine*; Apr 1, 2019; 199(7):925-928; PMID 30605350
21. Bailey O, **Combs D**, Sans-Fuentes M, Havens C, Poongkunran C, Patel S, Berryhill S, Provencio N, Quan SF, Parthasarathy S; Delayed sleep time in African Americans and depression in a community-based population; *Journal of Clinical Sleep Medicine*; Jun 15, 2019; 15(6):857-864; PMID: 31138383
22. Tubbs AS, **Combs D**, Grandner MA, Parthasarathy S; Obstructive Sleep Apnea in Jacobsen Syndrome; *Sleep and Vigilance*; April 2019; <https://doi.org/10.1007/s41782-019-00060-w>
23. Tubbs AS, Grandner MA, **Combs D**; Refractory insomnia in an adolescent with total blindness; *Yale Journal of Biology and Medicine*; Jun 27, 2019; 92(2):201-204; PMID: 31249480
24. Berryhill, S Morton CJ, Dean A, Berryhill A, Provencio-Dean N, Patel, SI, Estep, L, **Combs D**, Gerald LB, Krishnan JA, Parthasarathy S. Effect of Wearables on Sleep in Healthy Individuals: A Randomized Cross-Over Trial and Validation Study. *Journal of Clinical Sleep Medicine*. May 15 2020; 16(5):775-783; PMID 32043961

25. Pandey A, Mereddy S, **Combs D**, Shetty S, Patel S, Mashaqi S, Seixas A, Littlewood K, Jean-Louis G. Parthasarathy S. Socioeconomic Inequities in Adherence to Positive Airway Pressure Therapy in Population Level Analysis. *Journal of Clinical Medicine*. February 6, 2020; 9(2):442; PMID 32041146
26. **Combs D**, Edgin JO, Klewer S, Barber BJ, Morgan WJ, Hsu CH, Abraham I, Parthasarathy S. Obstructive sleep apnea and neurocognitive impairment in children with congenital heart disease. *CHEST*. 2020 Sep;158(3):1208-1217; PMID 32222588
27. **Combs D**, Parthasarathy S. Nocturnal oxygen for high altitude travel in patients with COPD. *JAMA Network Open*. Jun 22 2020; 3(6):e208022; PMID 32568396
28. Patel S, **Combs D**, Parthasarathy S. Sleep Apnea 20/20: A 20-year Cohort that continues to inform the next 20 years. *Journal of Clinical Sleep Medicine*. Dec 17, 2020; 16(S1):27-28; PMID 33054968
29. Mashaqi S, Mansour H, Alameddin H, **Combs D**, Patel S, Estep L, Parthasarathy S. The Cross-Talk Between Obstructive Sleep Apnea and Cardiovascular Remodeling; Matrix Metalloproteinase-9 as a Messenger – A Literature Review. *Journal of Clinical Sleep Medicine*. Mar 1, 2021;17(3):567-591; PMID 33108267
30. **Combs D**, Hsu CH, Bailey O, Patel S, Mashaqi S, Estep L, Provencio-Dean, N, Lopez S, Parthasarathy S. Differences in sleep timing and related effects between African Americans and non-Hispanic Whites. *Journal of Clinical Sleep Medicine*. May 1, 2021; 17(5):897-908. PMID 33382030
31. Mashaqi S, Patel SI, **Combs D**, Estep L, Helmick S, Machamer J, Parthasarathy S. The Hypoglossal Nerve Stimulation as a Novel Therapy for Treating Obstructive Sleep Apnea – A literature Review. *Int J Environ Res Public Health*. 2021 Feb 9;18(4):1642; PMID 33572156
32. Knobbe K, Partha M, Seckeler MD, Klewer S, Hsu CH, Edgin J, Morgan WJ, Provencio-Dean N, Lopez S, Parthasarathy S, **Combs D**. Sleep problems are associated with neurodevelopmental problems and decreased health-related quality of life in children with Fontan circulation. *J Am Heart Assoc*. 2021 October 20; 10:e021749; PMID 34668394

Electronic Publications

1. **Combs D**, Parthasarathy S; Pediatric Populations at High Risk for Sleep Apnea; Sleep Education.org. <http://sleepeducation.org/docs/default-document-library/nhsap-peds-high-risk-for-sleep-apnea.pdf>

CONFERENCES/SCHOLARLY PRESENTATIONS

Colloquia

Use of the receptor tyrosine kinase inhibitor MP470 in synovial sarcoma. Summer Institute on Medical Ignorance final oral report. Tucson, AZ. July 2007.

Neurocognitive Function in Melanoma Patients Treated with Interferon alpha-2b. Summer Institute on Medical Ignorance final oral report. Tucson, AZ. July 2008.

MP470, a Novel Agent for the Treatment of Synovial Sarcoma. Research Distinction Track Final Presentation. Tucson, AZ. April 2009.

Symposia/Conferences

Invited

Sleep Research Society Implementation Science Workshop, Seattle, WA. June 2015.

Update on Management of Sleep Disordered Breathing in Children. Pediatrics in the Desert. Tucson, AZ November 2015.

Sleep-disordered breathing in congenital heart disease. Invited lecture at the National University of Taiwan. Taipei, Taiwan, June 2017.

Update on Obstructive Sleep Apnea Treatment Options for Children. ENT in the Desert. Tucson, AZ February 2018.

Effects of Marijuana on Sleep. Invited lecture at Scientific Aspects of Medical Marijuana Conference, Phoenix, AZ March 2018.

Sleep Apnea in Children with Down Syndrome. Invited lecture at NIH INCLUDE Project workshop on Clinical Trials in Down syndrome for Co-occurring Conditions across the Lifespan, Bethesda MD May 2020.

Medications for Obstructive Sleep Apnea in Children with Down Syndrome. Invited lecture at NIH INCLUDE Project workshop on Clinical Trials in Down syndrome for Co-occurring Conditions across the Lifespan, Bethesda MD May 2020.

Invited participant, working group on respiratory and airway conditions for NIH INCLUDE Project workshop on Down Syndrome Research: The Intersection of Basic Science and Clinical Cohort Development, Bethesda MD November 2020.

Medications for Obstructive Sleep Apnea in Children with Down Syndrome. Invited Lecture at the New England Down Syndrome Symposium, Massachusetts Institute of Technology, Cambridge MA November 2020.

Submitted

Clarifying the role of the fusion protein SYT-SSX in synovial sarcoma. Poster presentation for 17th annual Undergraduate Biology Research conference. Tucson, AZ. January 2006.

The synovial sarcoma associated fusion protein SYT-SSX1 antagonizes the retinoblastoma protein inhibiting oncogene E7. Poster presentation for 18th annual Undergraduate Biology Research conference. Tucson, AZ. January 2007.

Testing a Therapeutic Pharmaceutical for Synovial Sarcoma. Poster presentation for 19th annual Undergraduate Biology Research conference. Tucson, AZ. January 2008.

The Novel Multi-Targeted Receptor Tyrosine Kinase Inhibitor MP470 Inhibits Synovial Sarcoma Proliferation In Vitro. Western Student Medical Research Forum. Carmel, CA. February 2008.

Activity of the multi-targeted, receptor tyrosine kinase inhibitor MP470 against synovial sarcoma cells. Poster presentation for the 99th annual meeting of the American Association for Cancer Research. San Diego, CA. April 2008

Effects of high dose interferon on memory in melanoma patients. Poster presentation for 6th annual International Melanoma Conference. Boston, MA. November 2009.

Screening tools for interferon-related cognitive decline in melanoma patients. Poster Presentation for 2010 American Society of Clinical Oncology Annual Meeting. Chicago, IL. June 2010.

Use of Rapid PDSA Cycles to Improve Pediatric Resident Handoffs. Poster presentation at Society of Hospital Medicine Annual Meeting. San Diego, CA. April 2012.

Incidence of delirium in children with cancer. Poster presentation at American Society for Pediatric Hematology Oncology 27th annual meeting. Chicago, IL. May 2014.

Prevalence of Sleep-Disordered Breathing in Children with Congenital Heart Disease. Poster presentation at 2015 International meeting of the American Thoracic Society. Denver, CO. May 2015

Development of a Modified STOP-Bang Tool for Adolescent Children. Poster presentation at Associated Professional Sleep Societies 2015 annual meeting. Seattle, WA. June 2015.

Sleep-Disordered Breathing is Associated with Impaired IQ in Children with Congenital Heart Disease. 14th International Symposium on Sleep and Breathing. Porto de Galinhas, Pernambuco, Brazil, October 2015.

Sleep-disordered breathing is associated with increased mortality among hospitalized infants with congenital heart disease. 2016 meeting of the Associated Professional Sleep Societies. Denver, CO. June 2016.

Impact of insomnia in children in a longitudinal seven year cohort. 2016 meeting of the Associated Professional Sleep Societies. Denver, CO. June 2016.

Sleep-disordered breathing is associated with neurocognitive impairment in children with congenital heart disease. SLEEP 2018 annual meeting, Baltimore, MD June 2018.

Peer-Reviewed Abstracts

Combs D, Cranmer LD, Trevor K. The novel multi-targeted receptor tyrosine kinase inhibitor MP470 inhibits synovial sarcoma proliferation in vitro. *Journal of Investigative Medicine*, Vol. 56 (1), 224-225, 2008.

Trevor K, **Combs D**, Mahadevan D, Bearss D, Cranmer L. Activity of the multi-targeted, receptor tyrosine kinase inhibitor MP470 against synovial sarcoma cells [abstract]. In: *Proceedings of the 99th Annual Meeting of the American Association for Cancer Research*; April 2008 ; San Diego, CA. Philadelphia (PA): AACR; 2008. [Abstract.] nr 4891.

Combs D, Baker A, Fu J, Herring A, Jeter J, Cranmer L. Feasibility study of neurocognitive assessment of melanoma patients treated with adjuvant interferon. *Journal of Clinical Oncology* 27, 2009 (suppl; abstr e20567).

Combs D, Baker A, Herring A, Trevor K, Jeter J, Cranmer L. Effects of high dose interferon on memory in melanoma patients. *Pigment Cell and Melanoma Research* 22(6):866, December 2009.

Combs D, Baker A, Jordan S, Morgan S, Pestana L, Herring A, Jeter J, Hersch E, Cranmer LD. Screening tools for interferon-related cognitive decline in melanoma patients. *Journal of Clinical Oncology* 28:7s, May 2010 (suppl; abstr 8539).

Kleifgen B, **Combs D**, Walker G, Franke H, Cramton R. Use of rapid PDSA cycles to improve pediatric resident handoffs. *Journal of Hospital Medicine* 7(S2), March 2012.

Combs D, Edgin J, Barber B, Morgan WJ, Parthasarathy S. Sleep-Disordered Breathing is Associated with Impaired IQ in Children with Congenital Heart Disease. 14th International Symposium on Sleep and Breathing. Porto de Galinhas, Pernambuco, Brazil, October 2015.

Oren E, **Combs D**, Fisher J, Goodwin JL, Billheimer D, Gerald JK, Clemens C, Brown M, Gerald LB. Impact of supervised asthma medication use on sleep outcomes of

elementary school children. 2016 International Meeting of the American Thoracic Society. San Francisco, CA. May 2016.

Daulat R, DeArmond R, **Combs D**, Shetty S, Parthasarathy S. Circadian Rhythms in Survivors of Critical Illness is Related to Acuity of Illness. 2016 International Meeting of the American Thoracic Society. San Francisco, CA. May 2016.

Combs D, Skrepnek G, Seckeler M, Barber B, Parthasarathy S. Sleep-disordered breathing is associated with increased mortality among hospitalized infants with congenital heart disease. 2016 meeting of the Associated Professional Sleep Societies. Denver, CO. June 2016.

Mereddy S, Pandey A, **Combs D**, Shetty S, Jean-Luis G, Parthasarathy S. Altitudinal Central Apneas and Adherence to Positive Airway Pressure Therapy. 2017 International Meeting of the American Thoracic Society. Washington, D.C. May 2017.

Pandey A, Mereddy S, **Combs D**, Shetty S, Jean-Luis G, Parthasarathy S. Health Disparities in Adherence to Positive Airway Pressure Therapy in Population Level Analysis. 2017 International Meeting of the American Thoracic Society. Washington, D.C. May 2017.

Combs D, Goodwin JL, Quan SF, Morgan WJ, Edgin JO, Parthasarathy S. Mother knows best? Comparing child and parent report of sleep parameters with polysomnography. 2017 meeting of the Associated Professional Sleep Societies. Boston, MA June 2017.

Combs D, Edgin JO, Barber B, Morgan WJ, Hsu CH, Abraham I, Parthasarathy S. Sleep-disordered breathing is associated with memory impairment in children with congenital heart disease. 15th International Symposium on Sleep and Breathing. Madison, WI, July 2017.

Wagner A, Mathews C, Chen M, Lenker C, **Combs D**, Phan H, Lord L, Konop G, Caffey F, Sonney J, Maddox MH, Troxler RB. Developing Web-based Education Modules on Pediatric Sleep Disorders for Primary Care Providers: An Interdisciplinary Approach. 9th Pediatric Sleep Medicine Conference. Amelia Island, FL. November 2017.

Troxler RB, Chen ML, **Combs D**, Lenker CV, Matthews C, Wagner A. Pediatric Sleep Health is Public Health: An Interdisciplinary Approach to Development of Web-Based Education Modules for Primary Care Providers. 2018 Association of Maternal & Child Health Programs Annual Conference, Arlington, VA. February 2018.

Combs D, Abraham I, Hsu CH, Morgan W, Bailey O, Parthasarathy S. Parent treatment preferences for mild obstructive sleep apnea in children. 2018 International Meeting of the American Thoracic Society. San Diego, CA, May 2018.

Bailey O, Sans-Fuentes M, Havens C, **Combs D**, Poongkunran C, Patel S, Berryhill S, Provencio N, Quan SF, Parthasarathy S. Delayed sleep time in African Americans and depression in a community-based population. 2018 meeting of the Associated Professional Sleep Societies. Baltimore, MD June 2018.

Combs D, Edgin JO, Barber B, Morgan WJ, Hsu CH, Abraham I, Parthasarathy S. Sleep-disordered breathing is associated with neurocognitive impairment in children with congenital heart disease. 2018 meeting of the Associated Professional Sleep Societies. Baltimore, MD June 2018.

Knitter J, Patel S, Bailey O, Poongkunran C, Flores-Martinez A, Martinez L, Kobayashi U, **Combs D**, Parthasarathy S. Comparison of Performance of Four Adaptive Servo Ventilation Devices in Patients with Complex Sleep Apnea. 2018 meeting of the Associated Professional Sleep Societies. Baltimore, MD June 2018.

Combs D, Edgin JO, Barber B, Klewer S, Morgan WJ, Hsu CH, Abraham I, Parthasarathy S. Obstructive Sleep Apnea is a Novel Risk Factor for Neurocognitive Impairment in Children with Congenital Heart Disease. 2018 American Heart Association Scientific Sessions. Chicago, IL November 2018.

Berryhill S, Patel SI, Provencio N, **Combs D**, Havens CM, Parthasarathy S. Cloud-Based Evaluation Of Wearable-Derived Sleep Data In Insomnia Trials. 2019 meeting of the Associated Professional Sleep Societies. San Antonio, TX June 2019.

Provencio N, Morton CJ, Wendel C, Berryhill S, Partha MT, Kulkarni H, **Combs D**, Patel SI, Desai, B, Quan SF, Parthasarathy S. EMR and Clinic Based Approaches for Recruiting Peer Support for Sleep Apnea. 2019 meeting of the Associated Professional Sleep Societies. San Antonio, TX June 2019.

Patel SI, Wendel C, Berryhill S, Provencio N, DeArmond R, Quan SF, **Combs D**, Skrepnek GH, Parthasarathy S. Health Benefits to Peers Participating in a Mentoring program for Treatment Adherence in Patients with Sleep Apnea. 2019 meeting of the Associated Professional Sleep Societies. San Antonio, TX June 2019.

Combs D, Abraham I, Hsu CH, Morgan WJ, Patel S, Parthasarathy S. Comparison of parent and child treatment preferences for obstructive sleep apnea. 2019 meeting of the Associated Professional Sleep Societies. San Antonio, TX June 2019.

De Armond R, Morton C, Patel SI, **Combs D**, Parthasarathy S. Sex as a Biological Variable on the Inflammatory Effects of Intermittent Hypoxia. 2019 meeting of the Associated Professional Sleep Societies. San Antonio, TX June 2019.

Patel SI, Vasquez M, Guerra S, **Combs D**, Parthasarathy S. Treatment of Sleep Disordered Breathing With Positive Airway Pressure Therapy Reduces The Number of Hospitalizations In A Large Cohort Of Patients With Heart Failure. 2019 American Heart Association Scientific Sessions. Philadelphia, PA November 2019.

Huang F, Patel SI, **Combs D**, Parthasarathy S. Mortality and hospitalization in patients with heart failure and sleep apnea: A retrospective study of positive airway pressure therapy in medicare beneficiaries. 2020 meeting of the Associated Professional Sleep Societies. Virtual meeting due to COVID-19 August 2020.

Combs D, Patel SI, Mashaqi S, Provencio-Dean N, Lopez S, Parthasarathy S. Objective differences in sleep timing between African Americans and Non-Hispanic Whites. 2020 meeting of the Associated Professional Sleep Societies. Virtual meeting due to COVID-19 August 2020.

Patel SI, Zareb W, Couderc JP, Xia X, LaFleur B, Torabzadeh E, Woosely R, Patel I, **Combs D**, Mashaqi S, Parthasarathy S. Repolarization Variability Predicts Cardiovascular Death In Obstructive Sleep Apnea. 2020 meeting of the Associated Professional Sleep Societies. Virtual meeting due to COVID-19 August 2020.

Parthasarathy S, Kukafka DS, Antonescu C, Patel SI, **Combs D**, Quan SF, Lee-Iannotti JK. Test Characteristics of a machine learned Electronic Medical Record Extractable tool for OSA Case Identification in a Community-based Population. 2020 meeting of the Associated Professional Sleep Societies. Virtual meeting due to COVID-19 August 2020.

Berryhill, S Morton CJ, Dean A, Berryhill A, Provencio-Dean N, Patel, SI, Estep, L, **Combs D**, Gerald LB, Krishnan JA, Parthasarathy S. Effect of Wearables on Sleep in Healthy Individuals: A Randomized Cross-Over Trial and Validation Study. 2020 meeting of the Associated Professional Sleep Societies. Virtual meeting due to COVID-19 August 2020.

Patel S, **Combs D**, Provencio-Dean N, Mashaqi S, Bhattacharjee R, Quan SF, Morton CJ, Wendel C, Parthasarathy S. Peer-intervention Can Reduce Health Disparities In Patients With Obstructive Sleep Apnea. 2020 meeting of the Associated Professional Sleep Societies. Virtual meeting due to COVID-19 August 2020.

Jain SV, Kondapalli K, Moskowitz A, **Combs D**, Parthasarathy S. Sleep Education Improves Screening for Sleep Disorders among Physicians and Residents in Primary Care and Neurology Specialties. 2020 meeting of the Associated Professional Sleep Societies. Virtual meeting due to COVID-19 August 2020.

Combs D, Fernandez V, Barber B, Morgan WJ, Hsu C, Andrews JG, Parthasarathy S, Klewer S, Seckeler M. Obstructive Sleep Apnea Is Associated with Cardiac Dysfunction In Children With Congenital Heart Disease. 2020 American Heart Association Scientific Sessions. Virtual meeting due to COVID-19 November 2020.

Patel SI, Zareba W, LaFleur B, Couderc JP, Xia X, Woosley RL, **Combs D**, Patel I, Mashaqi S, Parthasarathy S. The Relationship between Sleep Disordered Breathing, Markers of Ventricular Repolarization and Cardiovascular Mortality. 2021 meeting of the Associated Professional Sleep Societies. Virtual meeting due to COVID-19 June 2021.

Patel SI, Zareba W, LaFleur B, Couderc JP, Xia X, Woosley RL, **Combs D**, Patel I, Mashaqi S, Parthasarathy S. The association of QTc and QT Variability with Severity of Sleep Disordered Breathing. 2021 meeting of the Associated Professional Sleep Societies. Virtual meeting due to COVID-19 June 2021.

Robertson K, Seckeler M, Klewer S, Hsu CH, Edgin J, Provencio-Dean N, Lopez S, Parthasarathy S, **Combs D**. Sleep problems are associated with behavioral problems and decreased quality of life in children with Fontan circulation. 2021 meeting of the Associated Professional Sleep Societies. Virtual meeting due to COVID-19 June 2021.

Combs D, Partha M, Hsu CH, Edgin J, Seckeler M, Klewer S, Parthasarathy S, Cooper DS. Trouble sleeping predicts future decreased quality of life in young children with Fontan circulation. 2022 meeting of the Associated Professional Sleep Societies. Charlotte, NC. June 2022. Submitted.

AWARDED GRANTS AND CONTRACTS

IHS-1306-02505	2/27/2014 -1/13/2018
	\$2,117,118

“Peer-Driven Intervention as an Alternate Model of Care Delivery and Coordination for Sleep Apnea”

The primary purpose of this grant proposal is to integrate peer-driven intervention with an interactive voice response system that will improve patient-centered outcomes in patients with sleep apnea.

PI: Parthasarathy

Role: Co-investigator

American Academy of Sleep Medicine Foundation	6/1/2016-5/31/2019
Jr Faculty Award	\$74,389

“Neurocognitive Impairment in Children with Congenital Heart Disease and Sleep-Disordered Breathing”

This grant examined the role of sleep apnea as a treatable cause of neurocognitive impairment in children with congenital heart disease.

Role: PI

University of Arizona	10/1/2016-9/30/2017
Faculty Seed Grant	\$9,930

“Neurocognition and endothelial function in children with congenital heart disease and sleep-disordered breathing”

This grant examined the role of sleep apnea in endothelial and neurocognitive dysfunction in children with congenital heart disease.

Role: PI

American Academy of Sleep Medicine Foundation 1/1/2017-12/31/2017
Focused Projects Award \$19,999

“Improving screening for sleep disorders in children with epilepsy among pediatric providers”

This grant evaluated the use of a brief training intervention to improve recognition of sleep disorders in children with epilepsy by pediatricians.

PI: Jain

Role: Co-investigator

University of Arizona Health Sciences 2/1/2019-1/31/2021
Career Development Award \$80,400

“Obstructive sleep apnea, neurocognition and quality of life in children with congenital heart disease”

This grant provided 75% protected time for career development and research on the effects of OSA on cognition and quality of life in children with CHD. Salary support was ended upon receipt of my American Heart Association award.

Role: PI

American Heart Association 4/1/19-03/31/22
Career Development Award \$231,000
(19CDA34740005)

“Examining the role of obstructive sleep apnea in cognitive and quality of life impairment in children with CHD”

This grant evaluates the impact of obstructive sleep apnea on cognition, quality of life and endothelial function in children with congenital heart disease.

Role: PI

R61HL151254 9/15/2019-08/31/2022
NIH-NHLBI \$465,336

“Medications for Obstructive Sleep Apnea to Improve Cognition in Children with Down Syndrome (MOSAIC DS)”

This grant evaluates a novel therapy (atomoxetine and oxybutynin) for the treatment of obstructive sleep apnea in children with Down syndrome.

Role: PI

LuMind IDSC Foundation 6/1/2020-5/30/2021
\$15,000

“Neurocognitive and Language Evaluation in the ato-oxy treatment for OSA in children with Down Syndrome”

This grant is to obtain preliminary data on the short-term neurocognitive and language development effects of atomoxetine and oxybutynin in children with Down syndrome and obstructive sleep apnea.

Role: PI

Tab C

Curriculum Vitae

Date Prepared: September 24, 2021

Name: Charles A. Czeisler, Ph.D., M.D., F.R.C.P., F.A.P.S.

Office Address: Division of Sleep and Circadian Disorders
Brigham and Women's Hospital
221 Longwood Avenue, Suite 438
Boston, MA 02115

Work Phone: 617-732-4013

Work Email: charles_czeisler@hms.harvard.edu

Work FAX: 617-732-4015

Place of Birth: Chicago, Illinois

Education

1974	A.B. (<i>magna cum laude</i>)	Biochemistry and Molecular Biology	Harvard College, Cambridge, MA
1978	Ph.D.	Neuro- and Biobehavioral Sciences (William C. Dement M.D., Ph.D.)	Stanford University, Stanford, CA
1981	M.D.	Medical Doctor	Stanford University School of Medicine, Stanford, CA

Postdoctoral Training

1981-1983	Senior Fellow	Health Policy (David A. Hamburg, M.D.)	Center for Health Policy and Management, John F. Kennedy School of Government, Harvard University, Cambridge, MA
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Faculty Academic Appointments

1978	Adjunct Instructor	Biological Sciences	Graduate School of Arts and Sciences, Fordham University, Bronx, NY
1979	Lecturer	Undergraduate Studies	Stanford University
1979-1980	Research Associate	Physiology	Harvard Medical School, Boston, MA
1982-1983	Research Associate	Medicine	Harvard Medical School
1983-1987	Assistant Professor	Medicine	Harvard Medical School
1987-1998	Associate Professor	Medicine	Harvard Medical School
1994-	Affiliate Faculty	Program in Neuroscience	Harvard Medical School
1998-	Professor of Medicine	Medicine	Harvard Medical School

2004-	Frank Baldino, Jr., Ph.D. Professor of Sleep Medicine	Medicine	Harvard Medical School
2014-	Associate of Molecular and Cellular Biology	Molecular and Cellular Biology	Faculty of Arts and Sciences, Harvard University, Cambridge, MA
2019-	Senior Faculty	Harvard College Program in General Education	Faculty of Arts and Sciences, Harvard University

Appointments at Hospitals/Affiliated Institutions

1976-1978	Research Associate	Neurology	Montefiore Hospital, Albert Einstein College of Medicine, Bronx, NY
1982-1992	Associate Physician	Medicine, Endocrine Division	Brigham and Women's Hospital, Boston, MA
1992-1998	Physician	Medicine, Endocrine Division	Brigham and Women's Hospital, Boston, MA
1998-	Senior Physician	Medicine, Division of Sleep Medicine	Brigham and Women's Hospital, Boston, MA
1999-2014	Affiliate Faculty	Health, Science and Technology Program	Harvard Medical School/ Massachusetts Institute of Technology, Cambridge, MA

Other Professional Positions

1981-1993	Founder and Director	Center for Design of Industrial Schedules, Boston, MA
1991-1994	Consultant	Light Sciences, Inc., Braintree, MA
1993-1994	Consultant	ShiftWork Systems, Inc., Cambridge, MA
1996-	Member, Board of Trustees	Institute for Experimental Psychiatry Research Foundation, Milton, MA
2000-2011	Consultant	Cephalon, Inc., West Chester, PA (after 2005, Frazer, PA)
2001-2005	Consultant	Lifetrac, Inc., Biddeford, ME
2002-2003, 2006	Consultant	Pfizer, Inc., New York, NY
2003-2006	Member Circadian Rhythm Sleep Disorders Advisory Board, and Consultant	Takeda Pharmaceuticals North America, Inc., Lincolnshire, IL
2003-2011	Consultant	Respironics, Inc., Murrysville, PA
2004	Consultant	Unilever, Inc., London, UK
2004	Consultant and Member, Sleep-Wake Medicine Executive Advisory Board	Cephalon, Inc., Frazer, PA
2004-2007	Consultant and Member, Medical and Scientific Advisory Board	Hypnion, Inc., Lexington, MA
2004-2005,	Consultant/Expert Witness	Columbia River Bar Pilots, Astoria OR

2010		
2004-2013	Consultant	Sleep Multimedia, Inc.
2004-	Consultant	Vanda Pharmaceuticals, Inc., Washington DC
2005	Consultant	Warburg-Pincus
2005	Consultant	Morgan Stanley
2005	Consultant	Avera Pharmaceuticals, Inc., San Diego, CA
2005-2008	Consultant	Actelion Pharmaceuticals Ltd, Allschwil, Switzerland
2005-2010	Consultant	Norfolk Southern
2005-	Chair, Scientific Advisory Board	Vanda Pharmaceuticals, Inc., Washington DC
2007	Consultant	Fedex Kinko's/Ketchum Inc.
2007-2009	Consultant	Sepracor, Inc., Marlborough, MA
2007-2010	Consultant	Somnus Therapeutics, Inc., Bedminster, NJ
2007-2010	Consultant	Eli Lilly and Co., Indianapolis, IN
2008-2009	Consultant	Garda Síochána Inspectorate (Dublin, Ireland)
2008-2009	Consultant	Sanofi-Aventis, Inc.
2008-2010	Consultant	Johnson & Johnson
2008-2011	Consultant	Portland Trailblazers
2008-2011	Consultant	Koninklijke Philips Electronics, N.V.
2008-2013	Consultant and Member, Scientific Advisory Board	Zeo, Inc. (formerly Axon Labs, Inc.) Newton, MA
2009	Consultant/Expert Witness	Delta Airlines/Comair
2009-2010	Consultant/Expert Witness	Global Ground Support
2009-	Consultant	Boston Celtics
2010-2011	Consultant	Minnesota Timberwolves
2010-	Consultant/Expert Witness	Bombardier Inc.
2011	Consultant/Expert Witness	Celadon Trucking Services, Inc.
2011-2012	Consultant	Novartis/Gerson Lehman Group
2012	Consultant	Boston Bruins
2013	Consultant	Synchrony Healthcare Communications/Teva Pharmaceutical Industries Ltd.
2013	Consultant	Citgo and Valero
2013-2014	Consultant/Expert Witness	Michael Jackson's mother and children
2013-	Consultant	Boston Red Sox
2013-	Consultant	United Parcel Service
2013-	Consultant/Expert Witness	Purdue Pharma L.P.

Major Administrative Leadership Positions

Local

1976-1981	Project Director, Laboratory of Human Chronophysiology,	Department of Neurology, Montefiore Hospital
1983-1989	Director, Neuroendocrinology Laboratory	Brigham and Women's Hospital
1990-2001	Director, Laboratory for Circadian and Sleep Disorders Medicine	Endocrine Division, Department of Medicine, Brigham and Women's Hospital
1994-2001	Chief, Circadian, Neuroendocrine and Sleep Disorders Section	Endocrine Division, Department of Medicine, Brigham and Women's Hospital
1999-2004	Co-Director, Division of Sleep Medicine	Harvard Medical School
2001-2014	Chief, Division of Sleep Medicine	Department of Medicine, Brigham and Women's Hospital

2004- 2014-	Director, Division of Sleep Medicine Chief, Division of Sleep and Circadian Disorders	Harvard Medical School Departments of Medicine and Neurology, Brigham and Women's Hospital
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National and International

1997-2008	Team Leader, Human Performance Factors, Sleep and Chronobiology Team	National Space Biomedical Research Institute (NSBRI), Houston, Texas
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Committee Service

Local

1981-1988	Working Group on Health Promotion & Disease Prevention	Division of Health Policy, Harvard University Role: Executive Officer
1983-	Adams House Senior Common Room	Harvard College Role: Associate
1986-1989	Study Group on AIDS and Public Policy	Division of Health Policy Research and Education, Harvard University Role: Chairman
1989-1996	1986-1989 Graduate Medical Education Committee	Brigham and Women's Hospital Member
1993-1996	Long-range Planning Committee	Endocrine Division, Brigham and Women's Hospital Role: Member
1994	1993-1994 1995-1996 Computer Committee	Role: Chairman Endocrine Division, Brigham and Women's Hospital Role: Member
1994-1996	Ad-hoc Faculty Search Committee	Endocrine Division, Department of Medicine, Harvard Medical School Role: Chairman
1996-	Sleep Grand Rounds Organizing Committee	Division of Sleep Medicine, Brigham and Women's Hospital Role: Member
1997-	Clinical Investigation Committee	Research Council, Brigham and Women's Hospital Role: Member
1998-	Faculty Executive Committee	Division of Sleep Medicine, Harvard Medical School Role: Co-Chair
1998-	Education and Training Committee, Sleep, Circadian and Respiratory Neurobiology Training Program	Brigham and Women's Hospital Role: Chairman
1999-2000, 2002	Ad Hoc Committee of Evaluators for Professorial Appointment	Harvard Medical School Role: Member
2000-	Advisory Committee	John A. Hartford Foundation Center for Excellence in Geriatric Medicine, Division

		on Aging, Harvard Medical School Role: Member
2001-	Harvard Work Hours, Sleep and Safety Study Group	Division of Sleep Medicine, Harvard Medical School Role: Organizer
2001-	Executive Committee	Department of Medicine, Brigham and Women's Hospital Role: Member
2001-	Center for Clinical Investigation	Brigham and Women's Hospital Role: Member
2002-	Clinical Research Liaison Committee	Brigham and Women's Hospital Role: Member
2002-	General Clinical Research Center Steering Committee	Brigham and Women's Hospital Role: Member
2002-2003	Task Force on Graduate Medical Education	Partners HealthCare System Role: Member
2004	Dry Space Subcommittee, Executive Committee on Space (ECOS)	Brigham and Women's Hospital Role: Member
2006-	Ad Hoc Search Committee for the Peter C. Farrell Professor of Sleep Medicine	Harvard Medical School Role: Chair
2007-	Ad Hoc Search Committee for the Gerald E. McGinnis Professor of Sleep Medicine	Harvard Medical School Role: Chair
2007-	Ad Hoc Search Committee for a Professor of Medicine to serve as Director of the Sleep and Health Education Programs	Harvard Medical School Role: Chair
2007-	Division of Sleep Medicine Fellows Selection Committee	Brigham and Women's Hospital Role: Co-Chair
Regional		
1985-1986	Symposium on Health Promotion in the Workplace	Kellogg Foundation, Boston, MA Role: Co-chairman
2008	Discovery Panel	NASA Future Forums, Museum of Science, Boston, MA Role: Panelist
2008	Fatigue Management II: Technological and Pharmacological Approaches, Future Directions in Fatigue and Safety Research	Liberty Mutual, Hopkinton, MA Role: Working Group Member
2008	Massachusetts Special Commission on Drowsy Driving	Boston, MA Role: Special Consultant
2008-2009	Expert Panel on Obstetrics, Staffing and Communication Task Group	Betsy Lehman Center for Patient Safety, Boston, MA Role: Consultant
National and International		
1981-1982	Research Agenda for Health and Behavior	National Academy of Sciences (NAS) Institute of Medicine (IOM), Washington, DC Role: Task Force Member
1982-1983	Clinical Psychobiology Branch	National Institute of Mental Health (NIMH), Bethesda, MD

1983	Ad Hoc Advisory Group	Role: Consultant Institute of Chronobiology, New York Hospital, Cornell Medical School, White Plains, NY
1982-1984	The United States Olympic Committee	Role: Member Sports Medicine Division, Colorado Springs, CO
1984	Ad Hoc Subcommittee on Evaluation of Endocrine Studies in Space, Committee on Space Biology and Medicine	Role: Consultant National Research Council, National Academy of Sciences, Washington, DC
1989-1990	Research Briefing Panel on Basic Sleep Research	Role: Member Division of Health Science Policy, Institute of Medicine, NAS, Washington, DC
1989-1990	1989-1990 Scientific Review Branch	Role: Member National Institute of Neurological and Communicative Disorders and Stroke, NIH, Bethesda, MD
1989	Board of Scientific Counselors	Role: Advisory Consultant ADAMHA, National Institute of Mental Health (NIMH), Bethesda, MD
1989	General Clinical Research Center Site Visit Advisory Review Panel	Role: Ad hoc consultant Division of Research Resources, National Institutes of Health, Bethesda, MD
1989-1990	Planning Committee, Consensus Development Conference on Sleep Disorders in Older People	Role: Member National Institute on Aging and the Office of Medical Applications of Research, NIH, Bethesda, MD
1989-1991	Panel on Workload Transition, Committee on Behavioral and Social Sciences and Education	Role: Member National Research Council, National Academy of Sciences, Washington DC
1989-1991	Advisory Panel, New Developments in Neuroscience, "Biological Rhythms: Implications for the Worker"	Role: Member Office of Technology Assessment, United States Congress, Washington DC
1990-1991	Advisory Panel, Preflight Circadian Shifting of Shuttle Flight Crews, Space and Life Sciences Directorate	Role: Member National Aeronautics and Space Administration (NASA), Johnson Space Center (JSC), Houston, TX
1990	Biological Rhythms Task Force	Role: Member Mental Health Research Network, John D. and Catherine T. MacArthur Foundation, Chicago, IL
1990	Merit Award Advisory Review Panel	Role: Member National Institute on Aging (NIA), National Institutes of Health (NIH), Bethesda MD
1991	Future Approaches to the Basic Neurobiology of Sleep	Role: Member National Commission on Sleep Disorders Research, Bethesda MD
1991-	External Advisory Committee	Role: Workshop Panelist University of Virginia National Science and Technology Center, National Science

		Foundation
		Role: Member
1991	Committee for External Review of Sleep Research Center and Clinic	Department of Psychiatry, Stanford University, Stanford, CA
		Role: Chairman
1992	Neurolab Space Shuttle Research Planning Conference	Division of Basic Brain and Behavioral Sciences, National Institute of Mental Health/Life Sciences Division, NASA, Houston TX
		Role: Consultant
1992	Program Project Site Visit Review Panel	Scientific Review Office, National Institute on Aging, NIH, Bethesda MD
		Role: Chairman
1994	Operations Center	Nuclear Regulatory Commission (NRC), Washington, DC
		Role: Consultant
1994-	Advisory Committee	Night Operations and Human Chronobiology, Life and Environmental Sciences Division, Air Force Office of Scientific Research (AFOSR)
		Role: Member
1994	Focus Group	Neural Basis of Psychopathology, Neuroscience and Behavioral Science Division, NIMH
		Role: Member
1994	Work Hours, Sleepiness and Accidents Consensus Conference	National Institute for Psychosocial Factors and Health, Department of Clinical Neuroscience, Karolinska Institute, Stockholm
		Role: Panel Member
1994-	External Advisory Committee	General Clinical Research Center, University of Virginia, Charlottesville, VA
		Role: Member
1995	External Advisory Panel on "The Future of Sleep Research at NIMH"	NIMH
		Role: Member
1996	Workshop on Melatonin and Sleep	Neurobiology of Aging Branch, NIA
		Role: Panel Member
1996-1997	Advisory Group Spaceflight and Aging	Biology of Aging Program, NIA
		Role: Member
1996	Integrative, Regulatory and Behavioral Neurosciences Working Group	Neuroscience Integration Project, Division of Research Grants, NIH
		Role: Member
1997	Systems Physiology Workshop, Committee on Space Biology and Medicine	National Research Council, NAS
		Role: Panelist
1998-	Human Factors Research Team, Workshop to Develop Critical Path Roadmap	Johnson Space Center Human Space and Life Sciences Program Office and National Space Biomedical Research Institute, Houston, TX
		Role: Chair
2000-	Scientific Advisory Board	Alertness Management Initiative, Air

		Transport Association, Washington, DC Role: Member
2001	Scientific Advisory Panel, Mars Exploration Rover Surface Operations Human Factors Workshop	NASA Jet Propulsion Laboratory Role: Member
2000-2002	Ad hoc reviewer	Center for Scientific Review and National Center for Research Resources, NIH Role: Ad hoc reviewer
2003	External Advisory (Red Team II) Panel	International Space Station and Shuttle Utilization Reinvention (SSUR) Team, NASA Role: Member
2003	Workshop on Effects of Sleep Disorders and Sleep Restriction on Adherence to Prevention and Treatment Regimens	National Center on Sleep Disorders Research, National Heart, Lung and Blood Institute (NHLBI), NIH Role: Participant and Invited Speaker
2004	Workshop on Shift Work Sleep Disorder	National Sleep Foundation Workshop on Shift Work Sleep Disorder, Washington, DC Role: Invited Speaker and Session Chair
2005	Human System Integration Workshop	Behavioral Health and Performance Directorate, NASA, Houston, TX Role: Participant
2005	Committee on Sleep Medicine and Research	Institute of Medicine, National Academy of Sciences Role: Expert Consultant
2007	Medical Panel on Sleep Apnea and Commercial Truck Driving	Federal Motor Carrier Safety Administration (FMCSA), US Department of Transportation (DOT) Role: Panelist
2007	Committee on Optimizing Graduate Medical Trainee (Resident) Hours and Work Schedules to Improve Patient Safety	Institute of Medicine, National Academy of Sciences Role: Expert Consultant
2008	Fatigued Driving Committee	National Highway Traffic Safety Administration's (NHTSA) Office of Behavioral Safety Research, Bethesda, MD Role: Panelist
2008-	Steering Committee	Academic Alliance for Sleep Research Role: Member
2008-2011	Sleep Disorders Research Advisory Board	NHLBI, NIH Role: Member (2008-2011), Chair (2010- 2011)
2008	Consortium on Sleep Research	National Clinical and Translational Science Awards (NIH-CTSA) Role: HMS Representative
2008-	External Advisory Committee	Wisconsin Sleep Center, University of Wisconsin, Madison, WI Role: Member
2009	External Advisory Committee	Case Western Reserve University, Cleveland, OH

2009	Sleep Research Network	Role: Member
2012-	Medical Advisory Board	Role: Member (2009-), Chair Elect (2013), Chair 2013-2014
2014	External Review Committee	Circadian Sleep Disorders Network Role: Member
2014-2015	Panel Study on Truck Safety, Hours of Service, and Fatigue	Stanford Center for Sleep Sciences and Medicine, Stanford CA National Academy of Sciences (NAS), Washington, DC
2014	Selection Committee for Editor-in-Chief	Role: Task Force Member Sleep Health journal, National Sleep Foundation
2014	Drowsy Driving Forum	Role: Member National Transportation Safety Board, Washington DC
2015-	Scientific Advisory Board	Role: Panelist Institute of Digital Media and Child Development, Stony Brook NY
2015-	Sleep Disorders Council	Role: Member National Sleep Foundation, Arlington VA
2016-	Global Council on Brain Health	Role: Lead, Circadian Rhythm Disorders AARP in Collaboration with Age UK
2016-	Scientific Advisory Committee for the Stanford Sleep Study	Role: Issue Matter Expert on Sleep Klarman Family Foundation, Boston MA
2017-	Panel on Human Factors Science	Role: Member National Academies of Sciences, Engineering, and Medicine, Washington DC
		Role: Panel Member

Professional Societies

1975-	American Association for the Advancement of Science	
	1981	Symposium Co-Chairman
	1986, 1989	Symposium Speaker
1975-	International Society for Chronobiology	
1976-	Sleep Research Society	
	1980, 1981, 1985	Satellite Symposium Chairman and Co- Chairman
	1980	Chairman, Biological Rhythm Nomenclature Committee
	1982-5, 1988, 1990-5, 1997-8	Session Chairman
	1995-1999	Section Head, Circadian Rhythms Section
	1996-1999	Member, Board of Directors
	1996-1999	Member, Nominating Committee
	2003-2004	Chair, Research Committee
	2004-2005	President-Elect
	2004-2007	Chair, Presidential Task Force on Sleep and Public Policy
	2004-2007	Member, Executive Committee and Board

	2004-2007	of Directors
	2005-2006	Member, Board of Directors
	2006-2007	President
		President, Sleep Research Society
		Foundation
1979-	Society for Neuroscience	
	1986, 1999, 2007	Symposium speaker
1979-	American Physiological Society	
	1995	Workshop participant
1982-1988	Clinical Sleep Society	
	1987-1988	Fellow
1985-	American Sleep Disorders Association	
	1985-1989	Member, Nosology Committee
	1986-1990	Chairman, Subcommittee on Classification of Sleep Scheduling Disorders
	1988-	Fellow
	1989-1993	Member, Committee for Government Affairs and Public Policy
1985-	Association of Professional Sleep Societies	
	1986	Course Developer
	1986-1987	Member, Committee on Catastrophes, Sleep and Public Policy
	1987-8, 1993, 1995, 2000	Invited Symposium Speaker
	1988-1990	Chairman, Ad Hoc Government Advisory Steering Committee on Safety, Performance and Sleep
	1990, 1996	Symposium Chairman
	1992-3, 1998, 2002-3	Course Speaker
	1994	Workshop Organizer
	1997	Annual Meeting Keynote Speaker
	1997-1999	Member, Annual Meeting Program Committee
	2004-2007	Member, Board of Directors
1986-	Academy of Behavioral Medicine Research	Fellow
1988-1990	American Federation for Clinical Research	
1988-	Society for Research on Biological Rhythms	
	1988, 1992, 1994, 1998	Invited Symposium Speaker
	1993-1994	Member, Nominating Committee
	1996	Session Chairman
	2002	Keynote Speaker Annual Meeting
1989-1990	Northeastern Sleep Society	Chairman and Host Annual Meeting
1990-1995	National Sleep Foundation	Member, Board of Trustees
1990-	American Society for Clinical Investigation	Fellow
1995	American Physiological Society	Rapporteur, Study Group on Clocks and Human Biology
1997-	Association of American Physicians	
1998-1999,	World Federation of Sleep Research	
2004-2007	Societies	
	1998-1999	Member, Scientific Congress Committee,

	2004-2007	Third International Congress Member, Board of Directors
1998-1999	Association for Patient-Oriented Research	Member, Board of Trustees
2002	American Society for Photobiology	Symposium Co-Chair
2007-	Royal College of Physicians, London, U.K.	Honorary Fellow (F.R.C.P.)
2008-	American Clinical and Climatological Association	Elected as member
2014-2015	National Sleep Foundation	Chair, Board of Directors Chair, SAC Subcommittee: Circadian Rhythm Disorders Member, Education Committee
2018-	National Sleep Foundation	Chair, Sleep Timing and Variability Consensus Panel (STVCP)

Editorial Activities

Ad hoc Reviewer

Sleep

Proceedings of the National Academy of Sciences

Nature and Science of Sleep

Nature

Other Editorial Roles

1979-1980	Guest Editor	<i>Sleep</i>
1991-1997	Member, Editorial Board	<i>Sleep</i>
1995-1999	Member, Editorial Advisory Board	<i>Journal of Biological Rhythms</i>
1997	Guest Editor	<i>Journal of Biological Rhythms</i>
1997-2000	Member, Editorial Board	<i>Sleep Research Online</i>
1997-2000	Member, Editorial Board	<i>American Journal of Medicine</i>
2002-	Member, Editorial Board	<i>Sleep</i>
2009	Member, Editorial Board	<i>Nature and Science of Sleep</i>
2011	Member, Editorial Board	<i>Sleep and Biological Rhythms</i>
2012	Member, Advisory Board	<i>Sleep and Biological Rhythms</i>
2013-	Member, Editorial Advisory Board	<i>Journal of Biological Rhythms</i>
2014-	Member, Editorial Board	<i>Sleep Health</i>

Honors and Prizes

1970	Winner (National Top 40)	Westinghouse Science Talent Search
1970-1971	Honorary Freshman Scholarship	Harvard College
1972-1974	Harvard College Scholarship	Harvard College
1974-1975	Research Fellowship	Stanford Medical Scientist Training Program
1975-1981	Pre-doctoral Fellowship	NIH Medical Scientist Training Program (USPHS)
1981-1983	Josiah Macy Fellowship	
1982	Harvard Medical Society Lecture	

1983-1984	Christopher Walker Fellowship	
1987-1989	Sandoz Scholar in Medicine	
1988	Elliot David Weitzman Lecture	Cornell Medical College, Westchester, NY
1989	Distinguished Lecture	Massachusetts Institute of Technology Lincoln Lab
1990	Election as Fellow	American Society for Clinical Investigation
1991	Robert R.J. Hilker, M.D. Lectureship Award in Occupational Medicine	
1992	Keynote Lecture	International Brain Research Organization/Swiss chapter, Zurich
1992	Visiting Professor	Sinai Hospital of Baltimore/Johns Hopkins University School of Medicine, Baltimore, Maryland
1996	Plenary Lecture	Japanese Society for Sleep Research, Sapporo, Japan
1997	Keynote Speaker	Association of Professional Sleep Societies Annual Meeting, San Francisco, CA
1997	Election as Member	Association of American Physicians
1999	Phi Beta Kappa	Harvard College
2000	Keynote Speaker	Northeast Sleep Society
2001	“Aschoff’s Rule” International Award in Circadian Biology	
2002	E.H. Ahrens, Jr., Lecture Award	Association for Patient Oriented Research, Baltimore
2002	Keynote Speaker	Society for Research on Biological Rhythms, Amelia Island, FL
2002	William C. Dement Academic Achievement Award	American Academy of Sleep Medicine
2003	Keynote Speaker	Annual Patient Safety Research Conference, Agency for Healthcare Research and Quality, Washington, DC
2003	Plenary Speaker	World Congress of Chronobiology, Sapporo, Japan
2003	Distinguished Lecturer	Spaulding Rehabilitation Hospital, Boston, MA
2004	Plenary Speaker	Second International Forum on Sleep Disorders, Sanofi Aventis, Paris

2005	Keynote Speaker	Annual Meeting, Committee of Interns & Residents, Washington, DC	
2005	Gordon Wilson Lecturer	American Clinical and Climatological Association, Santa Barbara, CA	
2005	Plenary Address	X International Congress, Brazilian Sleep Research Society, Curitiba	
2005	Keynote Speaker	New Zealand Resident Doctors Association Professional Conference on Safer Working Hours in Medicine, Auckland, New Zealand	
2005	Visiting Professor of Anesthesia and Pfizer Lecturer in Sleep	University of Michigan Health Systems, Ann Arbor, MI	
2006	Distinguished Leaders in Medicine Lecturer	Faculty of Medicine, Dalhousie University, Halifax, Nova Scotia	
2006	Beckwith Family Lecturer and Beckwith Family Visiting Professor of Medicine	Brown University, Providence, Rhode Island	
2006	Healthy Sleep Community Award	National Sleep Foundation, Washington, DC	Harvard Work Hours, Health and Safety Group
2006	Director's Award for Scientific Leadership in Occupational Safety and Health (1 in nation)	National Institute for Occupational Safety and Health, Washington, DC	
2007	10th Annual J.Gerald Reves Duke Heart Center Lecture	Duke Medical Center, NC	
2007	Dorcas Cummings Memorial Lecture	72 nd Symposium: Clocks and Rhythms, Cold Spring Harbor Laboratory, NY	
2007	Lecturer	NIH Director's Wednesday Afternoon Lecture Series, Bethesda MD	
2007	Inducted to Honorary Fellowship (F.R.C.P.)	Royal College of Physicians, London, U.K.	
2007	Plenary Address	5 th Congress of the World Federation of Sleep Research and Sleep Medicine Societies, Worldsleee07, Cairns, Australia	
2007	Election as Corresponding Member	International Academy of Astronautics	
2008	Elected as Member	American Clinical and Climatological Association	
2008	Lifetime Achievement	National Sleep Foundation	

2008	Award Lord Adrian Gold Medal	Royal Society of Medicine, London, U.K.
2008	Distinguished Scientist Award	Sleep Research Society
2010	Keynote Speaker	Medical Scientist Training Program, Duke University Medical School
2010	Mark O. Hatfield Public Policy Award	American Academy of Sleep Medicine
2010	Harriet Hardy Award	New England College of Occupational and Environmental Medicine (NECOEM)
2010	23 rd Annual Catherine N. Stratton Aging Successfully Lecture	Massachusetts Institute of Technology
2010	Election as Member	Institute of Medicine of the National Academies
2010	Election as Full Member	International Academy of Astronautics
2011	Keynote Speaker	North East Sleep Society Annual Meeting
2011	Mary A. Carskadon Outstanding Educator Award	Sleep Research Society
2011	Keynote Speaker	World Association of Sleep Medicine
2012	Keynote Speaker	Harvard School of Public Health Symposium "Sleep and Shift Work: Optimizing Productivity and Health Management in the 24/7 Global Economy"
2014	Honorary Member Keynote Lecture	American Academy of Dental Sleep Medicine
2014	Golden Mind-Body Medicine Lecture	University of Buffalo
2014	JSC Director's Innovation Award	NASA, Johnson Space Center
2015	Elected Inaugural Fellow	American Physiological Society
2016	Keynote Speaker	Maryland Sleep Society Seventh Annual Scientific Meeting
2017	Michael S. Aldrich Commemorative Lectureship	University of Michigan
2018	Leonore Annenberg Lecturer	Annenberg Center for Health Sciences at Eisenhower Medical Center
2018	Keynote Lecture	Zurich Sleep Medicine Symposium 2018 / International

		Symposium of the CRPP Sleep & Health
2018	Pittendrigh-Aschoff Keynote Lecture	Society for Research on Biological Rhythms (SRBR)
2018	Green Cross for Safety Innovation Award for Brigham Health Sleep Matters Initiative	National Safety Council
2019	Peter C. Farrell Prize in Sleep Medicine	Harvard Medical School Division of Sleep Medicine
2019	J.E. Wallace Sterling Lifetime Achievement Award in Medicine	Stanford University School of Medicine Alumni Association
2019	Bernese Sleep Award	University of Bern, Bern, Switzerland

Report of Funded and Unfunded Projects

Funding Information

Past

1977-1979	Psychoneuroendocrine rhythms, aging and sleep disorders NIH R01 (National Institute on Aging) Project Director
1977-1979	Psychoneuroendocrine rhythms and sleep disorders NIH P01 (National Institute of Mental Health) Project Director
1979-1981	Psychoneuroendocrine rhythms, aging and sleep disorders NIH R01 (National Institute on Aging) Co-I: Project Director
1979-1981	Psychoneuroendocrine rhythms and sleep disorders NIH P01 (National Institute of Mental Health) Co-I: Project Director
1981-1983	Development of method to assess endogenous circadian phase/amplitude Peter Bent Brigham Hospital BRSG Grant PI
1983-1985	Disrupted sleep in the elderly: circadian etiology NIH R01 (National Institute on Aging) PI
1983-1984	Continuous vigilance simulator with real-time neuroendocrine correlation Air Force Office of Scientific Research; Department of Defense University Research Instrumentation Award PI
1983-1984	A chronobiotic study of quazepam Schering Plough Pharmaceutical Corporation PI
1983-1984	Circadian rhythms and athletic performance United States Olympic Committee Subcontract PI
1984-1986	The workplace: an opportunity for health promotion

W.K. Kellogg Foundation
Executive Officer

1985-1990 Disrupted sleep in the elderly: circadian etiology
NIH R01 (National Institute on Aging) competitive renewal for grant years 3-7
PI

1985-1986 Development of a method to assess the period and amplitude of the endogenous circadian oscillator
Brigham and Women's Hospital BRSG Grant
PI

1985-1988 Reproductive function in women: circadian interaction
NIH R01 (NICHD)
PI

1986-1987 Brigham and Women's Hospital BRSG Grant
PI

1987-1988 Occupational reproductive hazards - rotating shiftwork
March of Dimes Birth Defect Foundation
Co-I

1988-1989 Phase response curve to light in human subjects
Brigham and Women's Hospital BRSG Grant
PI

1989-1990 Development program for resetting the human circadian pacemaker
National Aeronautics & Space Administration
PI

1989-1994 Treatment of circadian sleep disorders with bright light
NIH R01 (National Institute of Mental Health)
PI

1990-1991 Comparative effects of pravastatin and lovastatin on nighttime sleep and daytime performance
Bristol Myers-Squibb Company
Investigator

1990-1997 Disrupted sleep in the elderly: Response to phototherapy
NIH R01 (National Institute on Aging) competitive renewal for grant years 8-12
PI

1991-1993 Pre-launch adaptation of extended duration orbiter crew members to 12-hr shift operations:
Clinical trial with and without bright light exposure
National Aeronautics & Space Administration
PI

1991-1998 Sleep, aging and circadian rhythm disorders
NIH P01 (National Institute on Aging)
PI

1994-1995 Feasibility of evaluating effects of exogenous melatonin, delivered by transdermal therapeutic systems in chronic insomnia in the elderly
Alza Corporation
PI

1994 Pre-Definition: Clinical trial of melatonin as hypnotic for Neurolab crew
National Aeronautics & Space Administration
PI

1994 Antarctic research collaborative on sleep, concentration and fatigue
National Aeronautics & Space Administration
PI

1994-1995	Definition Phase: "Clinical trial of melatonin as hypnotic for Neurolab crew" National Aeronautics & Space Administration PI
1994-1997	Pre-launch adaptation of orbiter crew members to earlier shifts following exposure to a single bright light episode National Aeronautics & Space Administration PI
1994-1997	Effect of exercise on endogenous circadian period, sleep and performance Air Force Office of Scientific Research PI
1994-2001	Bright light treatment of shift rotation insomnia NIH R01 (National Heart, Lung & Blood Institute) PI
1995-1999	Clinical trial of melatonin as hypnotic for Neurolab crew (ground-based study program in support of Neurolab mission) NIH U01 (National Institute on Aging) PI
1995-2000	Clinical trial of the effect of caffeine on the circadian and homeostatic interaction underlying deterioration of neurobehavioral functioning with sleep deprivation Air Force Office of Scientific Research; Partnership in Research Excellence & Transition Subcontract PI
1995-2000	Flight-Based Protocol Aboard Neurolab Space Shuttle: Clinical trial of melatonin as hypnotic for Neurolab crew National Aeronautics & Space Administration PI
1995-2001	Treatment of circadian sleep disorders with bright light NIH R01 (National Institute of Mental Health) competitive renewal for grant years 6-10 PI
1996	Double-blind, placebo-controlled study to determine the effect of MK-0677 on sleep in elderly patients with sleep disturbances Merck Research Laboratories PI
1996-1997	A double-blind, placebo-controlled study to determine the effect of L-754,030 on light-induced melatonin suppression in healthy young men Merck Research Laboratories PI
1997-1999	Clinical trial of the effect of exercise on resetting of the endogenous circadian pacemaker Air Force Office of Scientific Research PI
1997-2000	Human Performance Factors, Sleep and Chronobiology Team National Space Biomedical Research Institute Team Leader
1997-2000	Circadian entrainment, sleep-wake regulation and neurobehavioral performance during extended duration space flight National Space Biomedical Research Institute PI
1997-2001	Evaluation of intermittent bright light exposure as a spaceflight countermeasure National Aeronautics & Space Administration PI
1998-2003	Training in sleep, circadian and respiratory neurobiology

NIH T32 (National Heart, Lung & Blood Institute)
PI

1998-2005 Disrupted sleep in the elderly: Response to phototherapy
NIH R01 (National Institute on Aging) competitive renewal for grant years 13-17
PI until 2001; Investigator thereafter

1999-2000 Polysomnographic Study
Merck Research Laboratories
PI

1999-2000 Multi-site investigation of provigil (modafinil) treatment for performance impairing
sleepiness associated with night shift work
Cephalon Laboratories
PI

1999-2000 Astronaut activity in space flight
National Aeronautics & Space Administration
PI

1999-2002 Circadian adaptation to night work in older people
NIH R01 (National Heart, Lung & Blood Institute - National Occupational Research
Initiative)
PI

1999-2006 Sleep, aging and circadian rhythm disorders
NIH P01 (National Institute on Aging) competitive renewal for grant years 6-10
PI

2000 Clinical trial of the effect of exercise on resetting of the endogenous circadian pacemaker
Air Force Office of Scientific Research
PI

2000-2004 Circadian entrainment, sleep-wake regulation and performance during space flight
National Space Biomedical Research Institute competitive renewal for grant years 4-6
PI

2000-2004 Human Performance Factors, Sleep and Chronobiology Team
National Space Biomedical Research Institute competitive renewal for grant years 4-6
Team Leader

2000-2005 Clinical trial of the effect of modafinil on the circadian and homeostatic interaction
underlying the deterioration of neurobehavioral functioning during jet lag and sleep
deprivation
Air Force Office of Scientific Research Partnership in Research Excellence & Transition
competitive renewal for grant years 6-10
Subcontract PI

2001-2002 A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the
Safety and Impact on Quality of Life of 12 Weeks of PROVIGIL® (Modafinil) Therapy at
Dosages of 200 and 300 mg Once Daily as Treatment for Adults With Excessive
Sleepiness Associated With Shift Work Sleep Disorder, Followed by a 12-Month Open-
Label Extension Period
Cephalon, Inc.
PI

2001-2003 A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the
Efficacy and Safety of 12 Weeks of PROVIGIL® (Modafinil) Therapy at a Dose of 200
mg as Treatment for Adults With Excessive Sleepiness Associated With Chronic Shift
Work Sleep Disorder, Followed by a 12-Month Open-Label Extension Period
Cephalon, Inc.
PI

2001-2004	Effects of extended work hours on ICU patient safety DHHS R01 (Agency for Healthcare Research and Quality) PI
2001-2005	After-effects of entrainment on human circadian period NIH R01 (National Institute of Neurological Disorders and Stroke) PI
2001-2006	Treatment of circadian sleep disorders with bright light NIH R01 (National Institute of Mental Health) competitive renewal for grant years 11-15 PI
2001-2006	Effects of Extended Work Hours on Intern Health & Safety CDC R01 (National Institute of Occupational Safety and Health) PI
2001-2007	Circadian adaptation to non-24-hour sleep-wake schedules NIH R01 (National Institute of Neurological Disorders and Stroke) PI
2001-2008	Bright light treatment of shift rotation insomnia NIH R01 (National Heart, Lung & Blood Institute) competitive renewal for grant years 6-9 PI
2002-2003	Pfizer, Inc. PI
2004-2005	A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of 12 Weeks of R-Modafinil Therapy at a Dose of 200 mg as Treatment for Adults With Excessive Sleepiness Associated With Chronic Shift Work Sleep Disorder, Followed by a 12-Month Open-Label Extension Period Cephalon, Inc. PI
2004-2008	Human Performance Factors, Sleep and Chronobiology Team National Space Biomedical Research Institute competitive renewal for grant years 7-10 Team Leader
2004-2008	Circadian entrainment, sleep-wake regulation and performance during space flight National Space Biomedical Research Institute competitive renewal for grant years 7-10 PI
2004-2008	Sleep Disorders Management, Health and Safety in Police CDC R01 (National Institute of Occupational Safety and Health) PI
2004-2009	Adaptation of Circadian Responses to Light Treatment NIH R01 (National Heart, Lung & Blood Institute) PI
2005-2006	Optimizing the assessment of circadian and sleep/wake regulatory determinants of human performance through state of the art analysis of electroencephalogram, ocular activity and motor activity AFOSR (DURIP) PI
2005-2007	Implementing reduced work hours for all ICU staff to improve patient safety NIH (Agency for Healthcare Research and Quality) Investigator
2005-2008	Melatonin supplementation in hypertensive patients with beta blockers NIH (National Center for Complementary and Alternative Medicine) Co-I
2005-2009	Testing the Effectiveness of a Comprehensive Fatigue Management for the Boston Police

Department of Justice (National Institute of Justice)
PI

2006-2008 Interaction of chronic sleep restriction and circadian misalignment on sleep and neuron-cognitive performance: developing a new model of sleep homeostasis
AFOSR
PI

2007-2008 Translating the science of alertness and performance from laboratory to field: Using state-of-the-art monitoring, imaging, and performance enhancement technologies to improve the alertness and safety of the military and civilian workforce
AFOSR (DURIP)
PI

2008 Procedural Complications Associated with Attending Physician Extended-Duration Work Shifts
RxFoundation
Investigator

2003-2008 Training in sleep, circadian and respiratory neurobiology
NIH T32 (National Heart, Lung & Blood Institute) 1 T32 HL07901
Competitive renewal for grant years 6-10
PI (\$2,536,335)
THE NHLBI's National Center for Sleep Disorders Research identified the need to train investigators as its highest priority. The Harvard Medical School Division of Sleep Medicine Program for Training in Sleep, Circadian and Respiratory Neurobiology, based at the Brigham and Women's Hospital, is designed to address this need. This program provides structured, comprehensive research training to prepare outstanding individuals for academic positions in the broad field of sleep science and sleep medicine.

2004-2009 Mechanism Underlying the Effects of Blue Light in Humans
NIH (National Center for Complementary and Alternative Medicine) R01 AT002129 (PI: Lockley)
Investigator (PI until 2005)
The goal of this proposal is to investigate the effects of different colors of light on human physiology, and in particular, test the claims that specific colors of light preferentially stimulate neurobiological, physiological and endocrinological systems. Using classical photobiological techniques, we will construct action spectra for the effects of different colors of light on a range of non-image forming responses in humans.

2005-2009 Disrupted sleep in the elderly: Response to phototherapy
NIH R01 (National Institute on Aging) R01 AG06072
competitive renewal for grant years 18-22
Investigator
The goals of this grant are to test an evening light treatment regimen designed to achieve an optimum phase relationship between sleep and the output of the circadian timing system in older people in order to improve objective and subjective sleep quality.

2008-2009 Effects of Acute Sleep Deprivation on Visual attention and Gaze Control
National Space Biomedical Research Institute HPF00003
PI (\$79,233)
The fundamental objective of this study is to identify the determinants (behavioral, visuomotor, microsleep-induced) of performance lapses (during the psychomotor vigilance task, PVT) under acute sleep deprivation, and to quantify whether those determinants change with circadian phase and/or homeostatic sleep pressure.

2005-2010 Photic and nonphotic input to the human circadian system
NIH (National Institute of Neurological Disorders and Stroke) R01 NS040982 (PI:

Lockley)

Competitive renewal for grant years 5-8

Investigator

We are testing the hypotheses that: Study 1) exposure to monochromatic light of 460 nm for 6.5 h in the early biological night will cause a 3 h delay in circadian phase and a 85% suppression in pineal melatonin production whereas exposure to the same photon density of 555 nm will have no effect on circadian phase or melatonin suppression (compared to 1.7 h delay and 37% suppression in sighted subjects); Study 2) Exposure to a non-photic schedule advanced by 0.4 h relative to baseline intrinsic period will cause a phase advance of period of 0.4 h.

2007-2010 Evaluation of the potential for translation to practice of a sleep disorders management program for police

CDC (National Institute of Occupational Safety and Health) R01OH009403

PI (\$150,847)

We propose (1) to evaluate the potential for translation of the Operation Healthy Sleep program through the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework to health behavior interventions; (2) to evaluate the cost, feasibility and sustainability of the Operation Healthy Sleep program through cost-benefit analysis; and (3) to evaluate the external validity of the Operation Healthy Sleep program by comparing health, safety and productivity outcomes obtained from the primary police sample (Massachusetts State Police) with those obtained from a parallel program in the Philadelphia Police Department and a nationwide sample of more than 4000 police officers participating in a web-based survey.

2009-2010 Operational evaluation of a photic countermeasure to improve alertness, performance, and mood during nightshift work on a 105-day simulated human exploration mission

National Space Biomedical Research Institute HFP00002

PI (\$221,235)

The purpose of this study is to validate the efficacy and operational feasibility of a photic countermeasure to facilitate adaptation to the 24.65-h Martian sol, thereby improving sleep and performance. We propose to address the following hypotheses: (1) afternoon and evening exposure to moderately bright light will establish a normal entrained circadian phase in subjects living on a 24.65-hour day; (2) afternoon and evening exposure to moderately bright light will result in improved sleep, enhanced alertness and mood; (3) afternoon and evening exposure to moderately bright light will maintain the neurobehavioral performance of crewmembers living on the Martian sol.

2009-2010 Operational evaluation of a photic countermeasure to improve alertness, performance, and mood during nightshift work on a 105-day simulated human exploration mission

National Space Biomedical Research Institute HFP00002

PI (\$221,235)

The purpose of this study is to validate the efficacy and operational feasibility of a photic countermeasure to facilitate adaptation to the 24.65-h Martian sol, thereby improving sleep and performance. We propose to address the following hypotheses: (1) afternoon and evening exposure to moderately bright light will establish a normal entrained circadian phase in subjects living on a 24.65-hour day; (2) afternoon and evening exposure to moderately bright light will result in improved sleep, enhanced alertness and mood; (3) afternoon and evening exposure to moderately bright light will maintain the neurobehavioral performance of crewmembers living on the Martian sol.

2006-2011 Treatment of circadian sleep disorders with bright light

NIH (National Institute of Mental Health) R01 MH045130

Competitive renewal for grant years 16-20

- PI (\$1,139,040)
In this study we would systematically assess the circadian phase-shifting, melatonin suppressing, and alertness-enhancing response to a monochromatic light stimulus, using a wavelength (460 nm) that has been shown to maximally stimulate the circadian system.
- 2008-2011 A Comprehensive Firefighter Fatigue Management Program 'Operation Healthy Sleep'
Department of Homeland Security FEMA EMW-2007-FP-02197
PI (\$793,651)
We propose to use a station-level, randomized experimental design to test the hypotheses that implementation of a Comprehensive Firefighter Fatigue Management Program will: (1) improve the mean total sleep, alertness and cognitive performance of firefighters; (2) improve firefighter safety, as determined by decreased rates of motor vehicle crashes and on-the-job injuries; (3) improve firefighters' performance, as determined by decreased response time; (4) improve firefighters' health, as determined by diagnosis and treatment of sleep disorders, improved general health indices and decreased number of 'sick' days; (5) improve firefighters' and families' job satisfaction and ability to cope with extended work hours.
- 2009-2012 Effects of the circadian clock and light on the production of estrogens
NIH R21ES017112 (PI: Lockley)
Investigator
In the current proposal, we would like to take advantage of remaining urine and plasma samples collected under previous federal funds (NIH/NASA). We have a unique opportunity to study the relationships between light, circadian rhythms, shiftwork and melatonin and estrogen endocrinology from \$1M-worth of prior research conducted under strictly controlled laboratory conditions. These data will allow us to test the specific hypotheses that; i) there are significant 24-hour diurnal and circadian rhythms in plasma estradiol and urinary estrone-3-glucuronide production; and ii) that these rhythms are inversely related to plasma melatonin and urinary 6-sulfatoxymelatonin, respectively; iii) plasma estradiol will be acutely elevated following suppression of plasma melatonin; and iv) that the circadian rhythm of estradiol will phase-shift in parallel with the melatonin rhythm during a simulated shift-work protocol.
- 2004-2011 Adaptation of circadian responses to light treatment (supplement)
NIH R01 HL077453-05
PI (\$787,401)
The primary aim is to study a fundamental property of the circadian pacemaker, which is the ability of photic history to change the efficacy of light stimuli in modulating circadian regulation. The study may reveal a new method to potentiate light therapy in the treatment of circadian rhythm disturbances.
- 2008-2012 Evaluation of Photic Countermeasures for Circadian Entrainment of Neurobehavioral Performance and Sleep-Wake Regulation Before and During Spaceflight
National Space Biomedical Research Institute HFP01601
PI (\$1,428,571)
This project will test the efficacy of exposure to blue-enriched light at a standard intensity for pre-launch and in-flight phase shifting.
- 2009-2012 Interactions of genetics, behavioral sleep loss, circadian rhythms & performance
NIH (National Institute on Aging) SupplementP01 AG09975-S2
PI (\$499,804)
We propose to study 6 healthy individuals with the PER34/4 genotype and 6 with the PER35/5 genotype. The protocol will include a 23-day inpatient stay with 2 weeks of chronic sleep restriction in a forced desynchrony procedure, which will enable us to investigate both the circadian and wake-dependent contributions to alertness and

- performance, followed by one 40-hr sleep deprivation, which will enable us to investigate the response to an episode of acute sleep deprivation following chronic sleep restriction. We will record sleep and waking EEG, and test for multiple aspects of cognitive functioning, alertness and mood.
- 2009-2012 National firefighter sleep disorders management program: translation to practice
Department of Homeland Security FEMA TBAEMW-2008-FP-02566
PI (\$787,721)
Work hours, fatigue, performance, health and safety in firefighters; screening for sleep disorders and referral for treatment.
- 2010-2012 A comprehensive review of the work hours, health and safety of Federal Air Marshals
FAMS
PI (\$354,330; NCE)
The goal of this program is to reduce the adverse consequences of fatigue on the Air Marshals' health, safety and performance. The overall goal will be to develop work-hour policies and guidelines, and education and training program and an efficient sleep disorders screening program that can be implemented to improve the health, safety and performance of Federal Air Marshals and thereby improve public safety nationally.
- 2006-2013 Sleep, aging and circadian rhythm disorders
NIH P01 (National Institute on Aging) P01 AG09975
Competitive renewal for grant years 11-15
PI (\$1,056,303; NCE)
This proposal seeks to address that gap in our knowledge by using a well-established laboratory model to study what differences may exist between the sleep efficiency of older and younger subjects under conditions of chronic sleep restriction (ratio 19 hours scheduled wake: 5 hours scheduled sleep), carried out on a forced-desynchrony protocol, and by assessing the recuperative capabilities under conditions of sleep extension following this restriction. A 'metabolic aging' experiment has been included with the goal of understanding the endocrine and cardiovascular consequences of sleep restriction in both young and older subjects.
- 2009-2013 Validation of assessment tests and countermeasures for detecting and mitigating changes in cognitive function during robotics operations
National Space Biomedical Research Institute NBPF02001 (PI: Lockley)
Investigator
We will test the effectiveness of blue-enriched light and/or caffeine as fatigue countermeasures during robotic and cognitive performance. Subjects will be exposed to short-wavelength enriched white light and/or continuous low-dose caffeine administration on the robotics performance days in a randomized, placebo-controlled within-subjects design
- 2008-2013 Training in sleep, circadian and respiratory neurobiology
NIH T32 (National Heart, Lung & Blood Institute) 1 T32 HL07901
Competitive renewal for grant years 11-15
PI
The NHLBI's National Center for Sleep Disorders Research identified the need to train investigators as its highest priority. The Harvard Medical School Division of Sleep Medicine Program for Training in Sleep, Circadian and Respiratory Neurobiology, based at the Brigham and Women's Hospital, is designed to address this need. This program provides structured, comprehensive research training to prepare outstanding individuals for academic positions in the broad field of sleep science and sleep medicine.
- 2007-2014 Desensitization of Circadian Responses to Light
NIH (National Institute of Neurological Disorders and Stroke) R01 NS054277

- PI (\$1,000,000; NCE)
The proposed experimental and modeling efforts are to quantify the influences of acute sleep deprivation (short-term homeostatic), chronic sleep restriction (long-term homeostatic), circadian rhythmicity, and their interactions on neurocognitive performance and to develop a new model of sleep homeostasis that can predict the effects of chronic sleep restriction.
- 2009-2014 Efficacy of melatonin treatment in a phase advance model of insomnia
NIH 1R01HL093279
PI (\$1,250,000)
We propose to test the chronobiotic and sleep promoting effects of melatonin in a phase advance model of insomnia: (1.) Test the hypothesis that melatonin administered prior to scheduled sleep will advance circadian phase, with the plasma cortisol rhythm used as the primary phase marker, in a dose-dependent manner when sleep is scheduled to occur 5 hours before habitual sleep time; (2.) Test the hypothesis that melatonin administered prior to scheduled sleep will increase sleep efficiency when sleep is scheduled to occur 5 hours before habitual sleep time.
- 2013-2014 Development of an Algorithm for Identifying Individuals who are Highly Vulnerable vs Highly Resistant to the Effects of Sleep Loss on Performance
DARPA
PI
This project seeks to develop measures to predict individual variability in response to acute and chronic sleep loss. We will analyze existing data from baseline rested performance tests in an attempt to derive measures that can predict subsequent response to acute sleep loss or chronic sleep restriction.
- 2013-2014 Sleep duration required to restore performance during chronic sleep restriction
NIH/NHLBI R01 HL114088 (PI: Klerman)
Investigator
To quantify to what extent the initial level and time course of dissipation of sleep inertia, the level of performance for hours 2-6 after awakening, and the rate of decline in performance with increased wake duration after 6 hours awake depend on the length of the prior sleep episode in addition to sleep:wake ratio and circadian phase.
- 2011-2014 Clinical trial of an intervention to reduce fatigue and improve safety and health in firefighters
FEMA EMW-2010-FP-00521
PI
We propose to conduct a station-level, randomized clinical trial of policies designed to maximize sleep opportunities during current 24-hour shifts to improve alertness, performance, health and safety in firefighters.
- 2010-2014 Evaluation of a photic countermeasure for mission controllers
NASA NNX10AF47G
Co-PI (\$481,181)
We propose to implement a Comprehensive Fatigue Management Program for the flight mission controllers program. The goals of this program are to reduce the adverse consequences of fatigue on the mission controllers' alertness, performance, health, and safety. The overall goals of our team include developing an online education training program and an efficient sleep disorders screening, evaluating the acceptability, feasibility and efficacy of a shorter wavelength photic countermeasure during operational night shifts to improve the alertness, performance, health and safety of mission controllers.
- 2009-2015 Effects of attending surgeon and obstetrician fatigue on operating room safety
NIH/NHLBI R01 HL095472

PI (\$1,000,000)

In this proposal we will conduct a prospective observational study in the operating rooms of two hospitals – a community hospital without resident-physicians, and an academic center where residents work as assistant surgeons – to evaluate the effects of sleep deprivation on the performance of attending surgeons and obstetrician / gynecologists.

2009-2015 Mechanisms underlying adverse health consequences of shift work
NIH R01HL094806 (PI: Scheer)

Investigator

We aim to determine the progressive physiological changes across a work week of realistic simulated shift work focusing on those metabolic, endocrine, inflammatory, and cardiovascular variables that are biomarkers of susceptibility to the development of diabetes, obesity, and cardiovascular disease. We will use a 14 day/night laboratory protocol involving a within-subject, randomized, cross-over design including a simulated night shift and day shift schedule using a formal battery of scheduled behaviors and light exposures in healthy day workers and shift workers.

2012-2015 Screening for Obstructive Sleep Apnea in National Football League Players
NFL Charities G.A.M.S. ID 839
PI (\$100,000)

This project will establish an NFL-wide system of identifying those at high risk of OSA and further evaluating those at high risk. The project will also establish a critical database that could guide team physicians on the diagnosis and management of OSA among NFL players. This will lead to improved cognitive and psychomotor performance in the short-term and reduced cardiometabolic risk in the long-term. The project also has the potential to raise awareness of the negative cardiovascular-related risks associated with OSA, a disease that is highly prevalent in our society at large. The increased awareness and involvement of NFL players in the project may motivate the general public to seek screening, evaluation and treatment, if necessary, which has the potential to substantially reduce morbidity and mortality due to CVD.

2012-2015 The ISS Dynamic Lighting Schedule: An In-Flight Lighting Countermeasure to Facilitate Circadian Adaptation, Improve Sleep and Enhance Alertness and Performance on the International Space Station
NSBRI HFP02801(PI: Lockley)

To study how new lighting would be used operationally to provide a countermeasure to shiftwork in a high-fidelity simulation of the ISS lighting environment and sleep patterns.

Co-Investigator

2001-2017 Flight-Based Protocol Aboard Space Shuttle: “Sleep-Wake Actigraphy and Light Exposure During Spaceflight
NASA NCC9-119
PI (\$1,340,327)

This project is designed to investigate sleep and circadian rhythm organization and the prevalence of space flight-induced insomnia, during short and long-duration space flight. This experiment will use state-of-the-art ambulatory technology to monitor sleep-wake activity patterns and light exposure in all crewmembers aboard Space Shuttle and International Space Station missions.

2010-2016 Sensitization of human circadian responses to light
NIH/NHLBI R01 HL94654
PI

The studies will examine the effect on the human circadian system of four different durations of dim-light sensitization prior to a standardized light treatment.

2012-2016 Ultra-short light pulses as efficient countermeasures for circadian misalignment and

- objective performance and subjective alertness decrements
NSBRI HFP02802 (PI: Klerman)
Investigator
The goal of this project is to explore sex differences in response to circadian and length of time awake factors on sleep and performance.
- 2012-2016 Sleep Duration Required to Restore Performance During Chronic Sleep Restriction
NIH/NHLBI R01 HL114088 (PI: Klerman)
Investigator
The goal of this project is to explore sex differences in response to circadian and length of time awake factors on sleep and performance.
- 2016-2017 Ambulance Crashes in the United States: 2000 – 2015.
Falck Foundation (PI: Czeisler)
The goal of this grant is to determine the incidence of ambulance crashes in the United States over the past 15 years. Report temporal trends in both fatal and non-fatal crashes and use multiple sources of data to describe characteristics of these crashes. We will also estimate the proportion of crashes where fatigue may have been a contributing factor.
- 2016-2017 Environmental Factors Associated with Sleep Deficiency during Spaceflight
NSBRI HFP04502 (PI: Barger)
Investigator
The major goals of this project are to test the hypotheses that (1) hypoxia will be associated with sleep deficiency; (2) increased noise will be associated with sleep deficiency; and (3) hypercapnia will be associated with sleep deficiency.
- 2016-2017 The Impact of Objectively Measured Sleep Deficiency and Circadian Misalignment on Performance during Spaceflight
NSBRI HFP04504 (PI: Barger)
Investigator
The major goal of this project is to test the hypothesis that sleep deficiency and circadian misalignment will be associated with performance decrements during spaceflight.
- 2013-2018 Impact of Eliminating Extended Duration Work Shifts on Resident Health and Safety
CDC/NIOSH R01 OH0103001 (PI: Barger)
Investigator
We propose to conduct a large-scale nationwide survey of interns, similar to that which we conducted from 2002 – 2007. We will collect work hours and sleep data as well as health and safety outcomes on monthly web-based surveys.
- 2013-2018 Training in sleep, circadian and respiratory neurobiology
NIH T32 (National Heart, Lung & Blood Institute) 1 T32 HL07901
Competitive renewal for grant years 16-21
PI
The NHLBI's National Center for Sleep Disorders Research identified the need to train investigators as its highest priority. The Harvard Medical School Division of Sleep Medicine Program for Training in Sleep, Circadian and Respiratory Neurobiology, based at the Brigham and Women's Hospital, is designed to address this need. This program provides structured, comprehensive research training to prepare outstanding individuals for academic positions in the broad field of sleep science and sleep medicine.
- 2013-2019 Treatment of Circadian Disruption from Shiftwork in Older Adults
NIH/NIA R01 AG044416 (PI: Duffy)
Investigator
Our proposed study will test in older workers a sleep timing and enhanced lighting

regimen that has been successful in allowing young workers to maintain optimal performance at night. Information from this study will be an important step in developing shift work treatments for the nearly 3 million older Americans who work night or rotating shift schedules.

- 2013-2018 Multi-Scale Modeling of Sleep Behaviors in Social Networks
NIH/NIGMS R01 GM105018
Co-PI (Co-PI: Klerman)
The purpose of this grant is to explore sleep behaviors and social networks in a college population. Using multi-modal data from different cohorts of undergraduates, we will develop the first statistical and multi-scale mathematical models of sleep dynamics within social networks based on sleep and circadian physiology.
- 2015-2019 Clinical Trial Evaluating the Impact of Sleep and Sleep Deprivation on the Cerebral Glymphatic System
ONR/N00014-15-1-2408
PI
The goals of this project are to test the hypothesis that the volume of Virchow-Robin spaces (VRs) is larger during sleep than during wakefulness; to test the hypothesis that the alteration of nonREM and REM states during sleep is associated with changes in the volume of VRs; to test the hypothesis that the volume of VRs is greater during deep nonREM sleep (N3) than during lighter nonREM sleep (N2) and to test the hypothesis that the volume of VRs is altered by prolonged wakefulness (sleep deprivation).
- 2012-2020 Multicenter trial of work-hour limits for PGY 2 & 3 resident work hours on patient safety
CCC
NIH/NHLBI U01 HL111478
Co-PI (\$8,249,567)
We propose to carry out a randomized study in six intensive care units nationwide that will test whether a scientifically-founded intervention schedule that: 1) limits second and third year resident physicians to 16 consecutive hours of work; 2) promotes sleep; and 3) minimizes chronic sleep restriction, will result in: a decrease in preventable injuries to patients, a decrease in the risk that resident physicians will suffer motor vehicle crashes, increased resident sleep, and increased resident vigilance.
- 2018-2020 CTA: Open-label Clinical Trial to evaluate the Efficacy of Sodium Oxybate (Xyrem) in the Treatment of two Under-recognized Clinical Conditions: Post-traumatic Narcolepsy and Post-traumatic Hypersomnia.
Jazz Pharmaceuticals, Inc.
PI
- Current**
- 2018-2023 Training in sleep, circadian and respiratory neurobiology
NIH T32 (National Heart, Lung & Blood Institute) 1 T32 HL07901
Competitive renewal for grant years 21-25
PI
The NHLBI's National Center for Sleep Disorders Research identified the need to train investigators as its highest priority. The Harvard Medical School Division of Sleep Medicine Program for Training in Sleep, Circadian and Respiratory Neurobiology, based

at the Brigham and Women's Hospital, is designed to address this need. This program provides structured, comprehensive research training to prepare outstanding individuals for academic positions in the broad field of sleep science and sleep medicine.

- 2013-2021 Sleep, Aging, and Circadian Rhythm Disorders
NIH/NIA P01 AG009975
Role: PI/PD (Principal Investigator/Program Director)
The central theme of this project is to differentiate the consequences of circadian disruption (while minimizing sleep loss) and sleep deficiency (while minimizing circadian disruption) on glucose regulation.
- 2014-2020 Development of Countermeasures Against Adverse Metabolic Effects of Shift Work
NIH/NHLBI R01 HL118601(PI: Scheer)
Role: Investigator
The goal of this application is to test whether manipulating the timing of food intake prevents the adverse metabolic effects of circadian misalignment, and whether desynchrony between the central circadian pacemaker and the behavioral cycle leads to internal desynchrony in humans.
- 2014-2019 Development and Testing of Biomarkers to Determine Individual Astronauts' Vulnerabilities to Behavioral Health Disruptions
NNX14AK53G (PI: Lockley)
Role: Investigator
This study will evaluate biomarkers that will test the sensitivity of various sleep and circadian challenges to differentiate individuals
- 2015-2020 Lighting Protocols for Exploration - HERA Campaign
NASA/NNX15AM28G (PI: Lockley)
Role: Investigator
The major goals of this project are to evaluate the efficacy of a combined countermeasure of light and exercise on alertness and performance.
- 2014-2021 Testing solid state lighting countermeasures to improve circadian adaptation, sleep, and performance during high fidelity analog and flight studies for the International Space Station
Thomas Jefferson University/NNX15AC14G (PI: Lockley)
Role: Investigator
The major goals of this project are to complete final ground-testing required before replacement of the current fluorescent General Luminaire Assemblies (GLA) with solid state (LED) lighting on the International Space Station, and to conduct the first flight studies to examine the operational impact of the new LED lighting to facilitate rapid circadian rhythm resetting, and improve alertness and sleep during missions.
- 2016-2021 Circadian Lipidomics in Constant Routine, Forced Desynchrony, and Non-lab Setting
NIH/NHLBI 5R01HL132556 (PI: Kristal)
Role: Investigator
The major goals of this project are to identify, optimize, validate, and to cross-validate a set of nested plasma lipidomics-based biomarker profiles that report circadian phase and alignment using well-characterized samples drawn from three constant routine protocols

and four forced desynchrony protocols.

- 2016-202 The Role of Circadian Periodicity in Human Cardiovascular Disease and Diabetes
NIH/NHLBI 5R01HL103607-05A1 (PI: Forman)
Role: Investigator
The major goals of this project are to examine the effects of melatonin supplementation on insulin sensitivity using a hypersulinemic euglycemic clamp and β -islet cell function measured using a hyperglycemic clamp. We will also evaluate the effects of supplementation on HbA1c as a secondary analysis
Role: Co-I
- 2019-2023 Impact of Lifting Work Hour Restrictions on First-Year Resident Safety, Health and Well-Being. R01OH011773 (Barger, Laura) 09/1/19-08/31/23 Centers for Disease Control (CDC) The study could have important public policy implications related to the health and safety of the more than 116,000 medical and surgical residents, who are the principal providers of medical care in academic medical centers throughout the United States. (PI: Barger LK)
Role: CoI
- 2019-2021 Clinical Trial—FAA Sleep Deprivation Study for Aviation Research: Comparison across multiple types of sleep deprivation. Contract 6973GH-19-D-00066 from Solicitation 6973GH-19-R-00147 (\$5,654,163.32) Federal Aviation Administration Aeronautical Center. The goals of this contract are: (i) To assess gene expression changes associated with reduced and mistimed sleep.; (ii) To explore the relationship between gene expression and neurobehavioral changes from reduced and mistimed sleep; (iii) To enhance general understanding of changes during reduced and mistimed sleep; and (iv) To analyze the concordance of sleep and circadian rhythm-related genetic variants with this study's results. (M-PIs: Klerman EB and Czeisler CA)I
Role: M-PI
- 2017-2021 CTA: Effect of Dupilumab on Sleep Apnea Severity in Patients with Chronic Rhinosinusitis. (PI: Wellman, D. Andrew) Regeneron Pharmaceuticals, Inc.
Role: CoI
- 2019-2023 CTA: Sleep Training Plan to Improve Individual Sleep, Health and Safety. The major goals of this project are to use personalized sleep app (Dayzz) to develop sleep training plans, improve participants' sleep and reduce overall healthcare costs. Dayzz Live Well Ltd. PI: Barger LK.
Role: Co-I
- Role: PI (Principal Investigator)

Report of Local Teaching and Training

Teaching of Students in Courses

Albert Einstein College of Medicine, Bronx, NY

1976-1977	Biological Rhythms in Man ~15 medical students	Department of Neuroscience Co-organizer and lecturer ; ~55 hours
1978	Neuroscience Course	

~150 medical students

Guest lecturer ; ~3 hours

Fordham University, Graduate School of Arts and Sciences, Bronx, NY

1978 Biology 69302: Introduction to Circadian
Oscillations in Biologic Systems
~30 graduate/undergraduate students Course Developer/instructor; ~75 hours

Stanford University, Stanford, CA

1979 Stanford Medical School: Fiscal and
Ideological Crisis. Stanford Workshop on
Political and Social Issues
~75 undergraduate & medical students Co-developer/instructor ~70 hours

1979 Psychiatry 235: Clinical and Experimental
Polysomnography
30 undergraduates Guest Lecturer; ~3 hours

Harvard College, Cambridge, MA

1982-1996 Molecular & Cellular Biology 286:
Biological Oscillations & Circadian Clocks
1982-1990; alternate yrs Faculty ~40 hours/year
15-20 undergraduates per year
1992-1996; alternate yrs Co-Organizer/
Faculty ~85 hr/year
~30 students/year

1983-1984, Adams House 116: Biological Clocks in
1989 Man
Undergraduate House Seminar Course ~60 hours/year
Developer and Teacher
15-20 undergraduates per year

1986-1987 Adams House 118: AIDS and Public Policy
Undergraduate House Seminar Course ~60 hours
Developer and Teacher
~18 undergraduates

1988 North House 120: AIDS: Emerging Ethical
and Policy Dilemmas
Undergraduate House Seminar Course ~50 hours
Developer and Teacher
~25 undergraduates

1988 AIDS Education and Outreach Student
Counselor Training Program
Group advisor and training session speaker

1988 "Circadian rhythms and entrainment:
endocrine aspects" North House Seminar
Guest lecturer

1996-2020 Molecular & Cellular Biology 186:
Circadian Biology: From Cellular
Oscillators to Sleep Regulation
Co-Organizer/Faculty (1996-2010); ~70 hours/year
Director (2011-)
50-110 undergraduates per year

2003 Harvard Alumni Association, Alumni
College

	Lecturer 200-300 alumni	~5 hours
2016-2019	Freshman Seminar FRSEM 22D Time for Sleep Director/Faculty 15 undergraduates per year	~90 hours per year
2018-2020	Molecular & Cellular Biology 186 (MCB186): Sleep and Circadian Clocks: From Biology to Public Health Director (2018-) 50-115 undergraduates per year	~70 hours/year
2019-2021	General Education 1038 (GenEd 1038): Sleep Course Director 225 undergraduates per year	~120 hours/year

Harvard Medical School, Boston, MA

1976	Weekly Research Seminar Series 10-15 graduate students	Department of Physiology Lecturer; ~5 hours
1982	Harvard Medical Society 150 medical students	Lecturer on human circadian physiology; ~5 hours
1979-1991, 1995	Physiology 225: Physiological Timing Systems 15-20 medical students, graduate students and undergraduates per year	~35 hours/year (as instructor 1979-1991) ~75 hour/year (as co-organizer 1995)
1995-1998	Neurobiology 337: Neurobiology of the Human Circadian Pacemaker Faculty doctoral thesis advisor, Program in Neuroscience, 1 doctoral student	60-80 hours/year
1996-2002	Continuing Education 61212: Diagnosis and Treatment of Sleep Disorders 60-70 postgraduate students/year	~45 hours/year (as Co-director) ~12 hours/year as organizing committee member and faculty ~6 hours/year as faculty member
2000-2003	Scholars in Clinical Science: Tools of Physiologic Investigation ~20 graduate students	8 hours

Harvard University Extension School, Cambridge, MA

2008	The Physiology of Sleep (BIOS E-210) Invited Guest Lecture, ~20 students	~5hours
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Harvard School of Public Health, Boston, MA

1986	Occupational Health Weekly Symposium ~30 graduate students, postdoctoral fellows, faculty	Guest lecturer; 2 hours
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Formal Teaching of Residents, Clinical Fellows and Research Fellows (post-docs)**Stanford Medical School, Stanford CA**

1977, 1979	Research Center and Sleep Disorders Clinic Seminar Series ~10 graduate students and postdoctoral fellows	Lecturer; ~5 hours/year
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Laboratory and Other Research Supervisory and Training Responsibilities**Brigham and Women's Hospital, Boston, MA**

1982-1988	College Work-Study training program in laboratory research techniques. Developer/supervisor	30 student-trainees/term, 3 week-long sessions/year
1995-2000	Special Emphasis Research Career Award Program, National Institute on Aging. Faculty sponsor.	2 junior faculty trainees

Harvard Medical School, Boston, MA

1983-1987	Research preceptor, Pre-doctoral Fellow. Medical Scientist Training Program	
2001-	Research Preceptor, HMS Student in HST Program. Division of Health Science and Technology (HMS/MIT)	1 medical student/year, 50-100 hours/year
1986,1987, 1990	Faculty mentor, Brigham-Beth Israel Medical Group Program. Summer Research Fellowship Program.	1 medical student/summer; 25-40 hours/summer
1986-1991	Faculty advisor. Medical student research traineeship	1 medical student/year; 40-60 hours/year
1993-1994	Oral Examination and Ph.D. Dissertation Examining Committees	
1994-1997	Mentor, Faculty Training Grants, for Charles Weitz, M.D., Assistant Professor of Neurobiology and Emery N. Brown, M.D., Ph.D., Assistant Professor of Anesthesiology, Harvard Medical School	
1994-1995, 2001	Faculty advisor. Research Rotation, Program in Neuroscience	1 doctoral student/year; 10-20 hours/year
1995-1998	Committee Member and/or Advisor. Program in Neuroscience	
2000-2004		
2001-2005	Research Preceptor, two HST students	40-50 hours/year
2002-2005	Research Preceptor, HMS student	20-30 hours/year
2002-	Mentor, Faculty Training Grant (NIH K08), for an Instructor of Pediatrics, Harvard Medical School	
2003-2004	Mentor, GCRC Medical Student Clinical Research Training Award, for two HMS students	

Harvard University Graduate School of Arts and Sciences, Cambridge, MA

1983-1986,	Oral Examination and Ph.D. Dissertation
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1994-1997 Examining Committees, Division of Applied Sciences; Co-advisor and Committee Member

Harvard College, Cambridge, MA

1981-1985, 1987-1988, 1992, 1994 1984	Biology 90r: Supervised Research. Faculty preceptor first semester, then undergraduate thesis advisor Biology 91r: Supervised Reading. Faculty preceptor, directed reading	1-2 undergraduates per year; ~50 hours/year 1 undergraduate; ~15 hours/year
1984	Economics 910r: Supervised Reading and Research. Faculty advisor, directed reading	1 undergraduate; ~15 hours/year
1984-1987	Psychology and Social Relations 990: Senior Tutorial. Faculty preceptor first semester, then undergraduate thesis advisor	1 undergraduate; ~50 hours/year
1994	Nathaniel Kleitman Undergraduate Summer Fellowship Program in Human Chronobiology. Faculty advisor	5 summer undergraduate students; ~10 hours
2002-2003	Biology 90r: Supervised Research. Undergraduate thesis advisor	

Formally Supervised Trainees

Brigham and Women's Hospital, Boston, MA

1983-1986,	Gary S. Richardson, M.D.
1988-1992	Research supervisor; Clinical Fellow Research Residency Program and Faculty sponsor for junior faculty research trainee, Physician Scientist Award Program, National Institute on Aging, NIH.
1985-1987	Joel Steinberg, M.D. Post-doctoral fellow advisor
1986-1988	Suzanne Rogacz, M.D. Endocrine Training Program Research supervisor, Post-doctoral fellow advisor, Faculty sponsor for junior faculty clinical research trainee. Clinical Associate Physician Award Program, General Clinical Research Program, National Center for Research Resources, National Institutes of Health.
1994-1996	Emery N. Brown, M.D., Ph.D./Professor of Health Sciences and Technology and Professor of Computational Neuroscience, Massachusetts Institute of Technology Professor of Anaesthesia, Harvard Medical School Massachusetts General Hospital Endocrine Training Program Research supervisor and Post-doctoral fellow advisor
DATE	Janis Anderson, Ph.D./Assistant Professor of Psychology, Department of Psychiatry, Harvard Medical School/Brigham and Women's Hospital Post-doctoral fellow advisor
1988-1990	Marie Dumont, Ph.D. Post-doctoral fellow advisor

Faculty Advisor, Pre-doctoral Fellow, Training Program in Sleep, Circadian and Respiratory Neurobiology, National Heart Lung and Blood Institute

1991 - 1995	Elizabeth B. Klerman, M.D., Ph.D./Associate Professor of Medicine, Division of Sleep Medicine, Harvard Medical School; Associate Physician, Division of Sleep Medicine, Department of Medicine Brigham and Women's Hospital Endocrine Training Program Research supervisor and Post-doctoral fellow advisor
1997 - 2000	Kenneth P. Wright Jr., Ph.D./Assistant Professor, Department of Integrative Physiology Director, Sleep and Chronobiology Laboratory, Centers for Neuroscience and the

Integrative Study of Work, University of Colorado at Boulder
 Endocrine Training Program Research supervisor and Post-doctoral fellow advisor
 1994 - 1999 Jamie M. Zeitzer, Ph.D./ Assistant Professor, Psychiatry and Behavioral Sciences, Stanford University and VA Palo Alto Health Care System, Palo Alto, CA
 1997 - 2004 Angela Ritz-De Cecco, Ph.D./Pharmacist, Switzerland
 2002 - 2005 Kurt A. Smith, M.D./ Resident and Clinical Instructor, Emergency Medicine, University of Cincinnati School of Medicine
 2003 - 2006 Martin W. Schoen, M.D./ Intern, Department of Internal Medicine, Naval Medical Center, San Diego

Faculty Advisor, Post-doctoral Fellow, Training Program in Sleep, Circadian and Respiratory Neurobiology, National Heart Lung and Blood Institute

1986 - 1989 Steven H. Strogatz, Ph.D./ Director of Center for Applied Mathematics; Professor of Theoretical and Applied Mechanics, Cornell University
 1991 - 1994 Ghada El-Hajj-Fuleihan, M.D./ Professor of Medicine and Director of the Calcium Metabolism and Osteoporosis Program, American University of Beirut Medical Center
 1992 - 1997 Diane B. Boivin, M.D., Ph.D./ Associate Professor, Psychiatry Medicine, McGill University, Sleep Disorders Physician, Psychiatry, Douglas Hospital; Director, Centre for Study and Treatment of Circadian Rhythms
 1993 - 1995 David Neri, Ph.D./ Deputy Director, Cognitive, Neural, and Biomolecular Science & Technology Division, Office of Naval Research
 1995 - 1998 James K. Wyatt, Ph.D., D ABSM/Assistant Professor, Behavioral Sciences, Rush Medical College; Director, Sleep Disorders Center, Rush University Medical Center; Fellow, American Academy of Sleep Medicine
 1996 - 1998 Sat Bir Khalsa, Ph.D./ Assistant Professor of Medicine, Division of Sleep Medicine, Harvard Medical School; Associate Neuroscientist, Division of Sleep Medicine, Department of Medicine, Brigham and Women's Hospital
 1996 - 2000 Todd Horowitz, Ph.D./Instructor In Ophthalmology, Harvard Medical School; Research Associate, Brigham and Women's Hospital
 1998 - 2000 Jeanne Duffy, M.B.A., Ph.D./ Associate Professor of Medicine, Division of Sleep Medicine, Harvard Medical School; Neuroscientist, Division of Sleep Medicine, Department of Medicine, Brigham and Women's Hospital
 1999 - 2003 Claude Gronfier, Ph.D./ Research Assoc., Inserm, France
 2000 - 2003 Steven Lockley, Ph.D./ Associate Professor of Medicine, Division of Sleep Medicine, Harvard Medical School; Neuroscientist, Division of Sleep Medicine, Department of Medicine, Brigham and Women's Hospital
 2000 - 2002 Laura K. Barger, Ph.D./ Instructor in Medicine, Division of Sleep Medicine, Harvard Medical School; Associate Physiologist, Division of Sleep Medicine, Department of Medicine, Brigham and Women's Hospital
 2006 - 2007 Christopher Carello, Ph.D./Medical Liaison, Eli Lilly and Company
 2004 - 2006 Julie Marie Gottselig, Ph.D./ Law student, New England School of Law
 2011- Michael Lee, Ph.D./ Research Fellow in Medicine, Brigham and Women's Hospital, Harvard Medical School
 2014- Nina Vujovic, Ph.D./ Research Fellow in Medicine, Brigham and Women's Hospital, Harvard Medical School

Faculty Co-Advisor, Pre- and Post-doctoral Fellows, Training Program in Sleep, Circadian and Respiratory Neurobiology, National Heart Lung and Blood Institute

1999 - 2001 Scott P. Grady, M.D., Ph.D./ Clinical Endocrinologist, Portland Diabetes and Endocrinology Center
 2002 - 2004 John Cronin, M.D./ Skaggs Scholar, The Scripps Research Institute; Associate Director,

	Scripps Clinic Sleep Center
2004	Shana E. McCormick, M.D./ Pediatric Resident, Massachusetts General Hospital
2002 - 2004	Nayantara Santhi, Ph.D./Research Fellow, Surrey Sleep Research Centre, Guildford U.K.
2003 - 2004	Anne-Marie Chang, Ph.D./Assistant Professor of Medicine, Pennsylvania State University
2003 - 2005	Frank A.J.L. Scheer, Ph.D./ Associate Director, Medical Chronobiology Program, Brigham and Women's Hospital; Assistant Professor of Medicine, Harvard Medical School; Associate Neuroscientist, Brigham and Women's Hospital
2005 - 2007	Joshua J. Gooley, Ph.D./ Lecturer in Medicine (academic, part-time), Harvard Medical School; Assistant Professor, Duke-NUS Graduate Medical School Singapore
2006 - 2008	Daniel Cohen, M.D./Associate Staff Neurologist, Beth Israel Deaconess Medical Center
2002 - 2010	Joseph T. Hull, Ph.D./ Research Fellow in Medicine, Division of Sleep Medicine, Brigham and Women's Hospital, Harvard Medical School
2004 - 2010	Erin E. Flynn-Evans/Research Psychologist, NASA
2004 - 2011	Melissa A. St. Hilaire, M.S., Ph.D./Research Fellow in Medicine, Division of Sleep Medicine, Department of Medicine, Brigham and Women's Hospital
2006 - 2011	Sean W. Cain, Ph.D./ Lecturer in Medicine (academic, part-time), Harvard Medical School; Senior Lecturer, Monash University, Australia.
2007 - 2011	Melodee Mograss, Ph.D./ Banting Scholar, The Research Institute of the McGill University Health Centre, Montreal, Quebec
2006 - 2013	Melanie Rüger, Ph.D./ Instructor in Medicine, Brigham and Women's Hospital, Harvard Medical School

Formal Teaching of Peers (e.g., CME and other continuing education courses)

Academy at Harvard Medical School, Boston, MA

2002	Medical Education Symposium: How the Brain Learns: Implications for Medical Education from the Neurosciences and Cognitive Theory	Lecture
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Brigham and Women's Hospital, Boston, MA

1986	"Sleep Disorders"	~40 CME students; ~3 hours
	Endocrine Division Postgraduate Medical Series	
1987	"Circadian rhythmicity and its disorders"	~60 CME students; ~3 hours
	Weekends in Internal Medicine	
Unknown	Patient Safety Imperative CME Course	
	Division of General Medicine	

Harvard T.H. Chan School of Public Health, Boston, MA

1990-1991	Work Schedules & Circadian Rhythms: Strategies for Improving Health, Safety, and Performance in Shift Work Operations	Faculty course director
2007-2009, 2011-2015	Ergonomics and Human Factors: Strategic Solutions for Workplace Safety and Health	Invited faculty member
2007	Epidemiology of the Occupational & Environmental Health Standards (EH 236)	Invited faculty member
2012	Sleep and Shift Work: Optimizing Productivity and Health Management in the 24/7 Global Economy Symposium	Invited faculty member and keynote speaker

Harvard Medical School, Boston, MA

2012	Physician Work Hours, Health and Patient Safety	Course Director and faculty member
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2013	The New Science of Resiliency and its Clinical Applications	Faculty member
2014	“Circadian Regulation of Sleep” for ‘Sleep! A CME Course for Physicians’	Faculty member
2015	“Consciousness” for ‘Sleep! A CME Course for Physicians’	Faculty member
2016	‘Sleep! A CME Course for Physicians’	Faculty member
2017	Circadian Control of Sleep for ‘Sleep! A CME Course for Physicians’	Faculty member

Local Invited Presentations

Stanford Medical School, Stanford CA

1978	Stanford Medical and Scientific Highlights Faculty Senate
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Harvard Medical School, Boston MA

1983	Harvard Medical School Faculty Meeting
1990	Shiftwork, circadian rhythms and sleep deprivation Harvard Medical School Committee on Hospital Safety
2000	Medical Ethics Forum: Medical Error: Patients in Peril? Division of Medical Ethics and Division of Sleep Medicine
2001	Conference on Resident Work Hours
2001	Sleep and Public Policy, New York Regional Council
2002	Combined Orthopedic Grand Rounds, Resident Work Hours, Safety and Health
2002	Keynote Speaker, 1 st Annual Sleep and Health Benefit Dinner Division of Sleep Medicine
2010	Organizing Committee and Speaker “Finding a research path for the identification of biomarkers of sleepiness” Division of Sleep Medicine
2012	Invited Speaker HMS Leadership Summit

Harvard College, Cambridge, MA

1988	Invited discussant, “The Ethics of AIDS Testing” Adams House, Harvard College
2013	Invited Speaker “Sleep, circadian rhythms, health and safety” Harvard Wellness Project, Harvard College

Harvard T.H. Chan School of Public Health, Boston, MA

2012	Invited discussant, “FIGHTING THE CLOCK: How America’s Sleep Deficit is Damaging Longterm Health” The Forum webcast, Harvard School of Public Health
2016	Invited Panel Member, “ASLEEP AT THE WHEEL: Drowsy Driving and Public Health” Presented in Collaboration with The Huffington Post The Forum webcast, Harvard School of Public Health

Harvard University, Cambridge, MA

2018	Invited Faculty “Mind/Brain Puzzle on Sleep” Harvard University Mind Brain Behavior Interfaculty Initiative (MBB)
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Beth Israel Hospital, Boston, MA

1983 Neurology Grand Rounds
 1986, 1988 Medical Grand Rounds
 1989, 1991
 1990 “Human circadian rhythmicity and its potential relevance to anesthesia research and clinical care”
 Anesthesia and Critical Care Grand Rounds
 1997, 2000 Psychiatry Grand Rounds

Beth Israel Deaconess Medical Center, Boston MA

2002 Endocrine Grand Rounds
 2002 Assessment of the Impact of Intern Work Hours on Patient Safety and Intern Health and Performance
 Chiefs’ Council
 2006 OB/GYN Grand Rounds

Brigham and Women's Hospital, Boston, MA

1983, 1996, Endocrine Grand Rounds
 2001
 1986, 1988, Medical Grand Rounds
 1991, 1993, Department of Medicine
 2001, 2002,
 2004, 2008
 1989 “Sleep Loss, Circadian Rhythms and the Hospital Intern”
 Graduate Medical Education Committee Program
 1994 “Circadian rhythms, sleep deprivation and emergency medicine”
 Emergency Medicine Rounds
 1995 “Advances in Circadian and Sleep Medicine, Disorders and Physiology”
 Medical Staff Grand Rounds
 2002 Noon House Staff Conference
 Department of Medicine
 2002 Work Hours, Sleep and Safety of Medical House Staff, Faculty Meeting and Executive Committee
 Department of Medicine
 2002 Sleep and the Healthcare Provider: Impact on Performance, Quality & Safety, Quality Rounds
 2004 Patient Safety Imperative, Division of General Medicine
 2007 Obstetrics and Gynecology Grand Rounds
 2009 “Sleep, Light and the Human Circadian Pacemaker”
 Sleep Grand Rounds
 2010 “Minding your brain: staying sharp”
 Men’s Health Program, Palm Beach, FL
 2013 Guest Faculty Speaker
 Women’s Health Luncheon, Boston MA
 2013 Guest Speaker
 Tye Health Coverage Fellowship, Boston MA
 2015 “A Sleep Epidemic”
 BWH Inspires Event, Palm Beach FL
 2015 “Sleep Deficiency and Public Health”
 Discover Brigham, Sleep Medicine Session, Brigham Research Institute, Boston MA
 2017 “Sleep Hygiene for Physician Shift Workers”
 Invited Speaker, Emergency Medicine Resilience Day, Boston MA

- 2018 Sleep Epidemic: Why are we sleeping less and What can we do about it?
Invited Faculty CME, BWH, Boston MA
- 2018 Speaker and Chair “Sleep Matters Initiative”
Discover Brigham, Sleep Medicine Session, Brigham Research Institute, Boston MA

Children’s Hospital, Boston, MA

- 1998 Neurosurgery Grand Rounds
- 2010 Invited Speaker “Introduction to Circadian Biology”
Updates in Pediatric Sleep Disorders Conference

Massachusetts Eye and Ear Infirmary, Boston, MA

- 1992 “Synchronization of the human circadian pacemaker by light: relevance to the treatment of
‘blind’ patients”
Research Symposium: “Advanced Concepts in Vision Science”

Massachusetts General Hospital, Boston, MA

- 1987 Chronobiology Research Group Seminar
Department of Pediatrics
- 1988, 2007 Endocrine Grand Rounds
- 1992 Neuroscience Lecture
- 2007 Anesthesia and Critical Care Grand Rounds
- 2013 Endocrine Grand Rounds

Partners HealthCare System

- 2001 Partners Chiefs’ Council
- 2002 Assessment of the Impact of Intern Work Hours on Patient Safety and Intern Health and
Performance
Partners Education Committee
- 2002 Work Hours, Health and Safety in Resident Physicians
BWH-MGH Joint Chiefs Council
- 2003 Physiologic Determinants of Alertness and Performance: Implications for Physician Work
Hours, Safety and Learning
Partners Faculty Development Conferences (at MGH and at BWH)
- 2015 Invited Speaker
1: Thought Leaders Lunch “Technology, Light and Sleep - Implications for Health and
Medicine”
2: “Sleep and Consciousness: Clinical Need versus Safety”
World Medical Innovation Forum, Boston MA

Spaulding Rehabilitation Hospital, Boston, MA

- 2003 Spaulding Distinguished Lecture

Veterans Administration Hospital, Jamaica Plain, MA

- 1986 Grand Rounds

Veterans Administration Hospital, Brockton, MA

- 1995 “Resetting the human circadian pacemaker with light”
Medical Grand Rounds

Veterans Administration Hospital, West Roxbury, MA

- 2004 Seminar Series

Report of Regional, National and International Invited Teaching and Presentations

Invited Presentations and Courses**Regional**

1978 Biological Clockwatchers Club
Boston, MA

Between
1985-1987 Invited Speaker.
Massachusetts Mental Health Center, Boston, MA

1986 Physiology course on circadian rhythmicity. Lecturer; ~25 medical students; ~3 hours
Boston University Medical School, Boston, MA

1987 Clinical Research Training Seminar, "Human circadian rhythmicity and its disorders"
Massachusetts Mental Health Center, Boston, MA

1988 Nursing and Human Resources Departments Seminar "Circadian rhythms, sleep
deprivation and the scheduling of nurses"
New England Medical Center, Boston MA

1988 Invited Speaker.
Northeastern Sleep Society, Boston MA

1989 Lincoln Laboratory Distinguished Lecture Series. Invited Speaker.
Massachusetts Institute of Technology, Cambridge MA

1990 Department of Biology Colloquium
Northeastern University, Boston MA

1992-1993 Biomedical Engineering Undergraduate Program. Faculty research advisor. 1
undergraduate; ~10 hours/year
Boston University, Boston, MA

1992-1999 Graduate Program in Biology: Physiology and Neurobiology. Faculty research sponsor; 1
doctoral student; ~20 hours/year
Northeastern University, Boston, MA

1994-1995 Biomedical Engineering Graduate Degree Program. Faculty research sponsor. 1 graduate
student; ~10 hours/year
Boston University, Boston, MA

Between
1994-1996 Invited Speaker.
Massachusetts Institute of Technology, Cambridge MA

1995-1998 Graduate Program in Cardiopulmonary Sciences. Faculty research sponsor; 1 graduate
student; ~20 hours/year
Northeastern University, Boston, MA

1996-1997 Biology 99d: Senior Research and Senior Honors in Biology. Faculty research sponsor; 1
undergraduate; ~10 hours/year
Brandeis University, Waltham, MA

1997 Medical Grand Rounds.
Boston University Medical Center, Boston MA

Between
1997-2001 Endocrine Grand Rounds
Risk Management Foundation, Boston, MA

Between
1997-2001 Invited Speaker.
New England College of Occupational and Environmental Medicine, Groveland MA

Between
1997-2001 Invited Speaker.
Boston Society of Neurology and Psychiatry, Boston MA

Between
2002-2008 Invited Speaker. Resident Physician Section
Massachusetts Medical Society, Waltham MA

Between
2002-2008 Medical Grand Rounds
New England Medical Center, Boston MA

Between
Advanced Neurobiology BI374. Guest Lecturer.

2002-2008 Colby College, Waterville, Maine

2003-2006 “Circadian Biology: From Clock Genes and Cellular Rhythms to Sleep Regulation”. Guest Lecturer.
NSF-Chautauqua Short Courses for College Teachers

2006 Psychiatry Grand Rounds.
Dartmouth Medical School, Lebanon, NH

2006 Beckwith Family Lecture. Medical Grand Rounds.
Brown University, Providence, RI

2007 Drowsy Driving Panel
National Conference of State Legislatures, Boston, MA

2008 “Bringing Circadian Rhythm Science into the Sleep Clinic”. Invited Speaker - Future of Clinical Sleep Medicine Conference.
Sleep HealthCenters, Boston

2009 Drowsy Driving Legislation. Invited Speaker
North East Sleep Society Conference, Boston MA

2009 Speaker in three symposia:
1. Addressing OSA in commercial drivers
2. Legislative initiative to reduce drowsy driving crashes
3. Inter-individual differences in the impact of sleep loss on neurobehavioral performance: Regulatory implications for the transportation industry
Fatigue Management in Transportation Operations 2009 International Conference, Boston MA

2010 Organizing Committee and Speaker
Sleep, Supervision and Safety Conference, Boston, MA

2011 Organizer and Speaker “Exploratory Seminar on Drowsy Driving”
Radcliffe Institute for Advanced Study, Harvard University, Cambridge MA

2011 Invited Speaker “Sleep to Thrive”
TEDx Cambridge ‘Thrive’, Cambridge MA

2012 Invited Panelist “Sleep Chat”
NIH Twitter Event, Boston MA

2012 Invited Speaker “Near-24-hour intrinsic period of the human circadian pacemaker: challenge for adaptation to the Martian sol”
Massachusetts Institute of Technology, Cambridge MA

2012 Invited Speaker, Discussion Panel “Measuring Sleepiness in Drivers: The Challenges and Controversies”
Association of Professional Sleep Societies Annual Meeting, Boston MA

2012 Invited Speaker, Discussion Panel “Body Mass Index is an Effective Measure for Occupational Screening of Employees at High Risk for Moderate to Severe Obstructive Sleep Apnea: Implications for DOT Commercial Driver Medical Examinations”
Association of Professional Sleep Societies Annual Meeting, Boston MA

2012 Chair Oral Presentation Session “Circadian Rhythms: Fiat Lux!”
Association of Professional Sleep Societies Annual Meeting, Boston MA

2014 Invited Speaker “Sleep, performance and health in a 24/7 culture”.
MIT Media Lab, Massachusetts Institute of Technology, Cambridge MA

2015 Panelist “School Community Meeting on School Start Time”
Latin Academy School (BLA), Boston MA

2015 Invited Speaker “The Science of Sleep and Health”
2015 World Congress on Angiogenesis, Angiogenesis Foundation, Boston MA

2015 Invited Speaker “Light, Sleep Disorders and the Working Environment”
Light in Sight Lecture Series, New England College of Optometry, Boston MA

2015 Invited Speaker “Sleep, circadian rhythms, health and performance”
Invited Speaker, Mind+Hand+Heart Wellness Initiative, Computer Science and Artificial Intelligence Lab (CSAIL) at MIT, Cambridge MA

2016 “Circadian Disorders”
Grand Rounds, Newton-Wellesley Hospital, Newton MA

2016 Invited Speaker – Panel “Drowsy Driving the Problem with the Accepted Practice”
2016 Northeast Transportation Safety Conference, Worcester MA

National

1978 Association for the Psychophysiological Study of Sleep. Invited Speaker

1978 NY Intradepartmental course on sleep. Guest lecturer; ~20 students; ~3 hours
Columbia University Psychiatric Institute, New York, NY

1980 Sleep Research Society. Satellite symposium chair on the Timing of REM Sleep

1978 Department of Biology course. Guest Lecturer.
University of New York, Stony Brook

1981 American Association for the Advancement of Science. Symposium co-chair

1982 Gordon Research Conference on Theoretical Biology and Biomathematics. Guest Lecturer.

1985 Sleep Research Society. Satellite symposium co-chair

1985 Postgraduate CME course,
Montefiore Hospital, Bronx NY

Between Satellite symposium co-chair.

1985-1987 Sleep Research Society

1986 American Association for the Advancement of Science. Invited Speaker.

1986 Society for Neuroscience. Invited Speaker.

1986 Academy of Behavioral Medicine Research. Invited Speaker.

1986 Grand Rounds, Carrier Foundation. Invited Speaker.

1986 “Impact of irregular work schedules on circadian training systems: Implications for scheduling emergency room specialists”. Invited Lecturer.
American College of Emergency Physicians, Washington DC.

1986 Postgraduate CME course, Sleep Research Society (faculty/course developer);

1987 Association of Professional Sleep Societies. Invited Speaker.

1987 Invited Speaker.
Rockefeller University, New York, NY.

1987 Invited Speaker.
NASA-Ames Research Center, Moffett Field, CA

1987 Invited Speaker.
Sandoz Pharmaceutical, Broomfield CO

1987 “Creating work schedules based on biological needs” Edison Electric Institute and Electrical Council of New England. Invited Speaker.

1987 Psychiatry Grand Rounds. Invited Speaker.
Cornell University Medical School, New York, NY

1987 Joint Endocrinology and Metabolism Rounds.
New York Hospital and Memorial Hospital. Invited Speaker New York, NY

1987 Palo Alto Clinical Monitoring Center. Invited Speaker.
Palo Alto, CA

1987 Sleep Disorders Medicine Postgraduate CME course. Guest Lecturer.
Medlantic Institute, Washington DC

1988 “Late luteal phase dysphoric disorder”. Invited Speaker.
National Institute of Mental Health Conference

1988 Elliot D. Weitzman Memorial Lecture.

1988 Cornell University Medical School, New York NY
 1988 New York Sleep Circle. Invited Speaker.
 1988 Invited Speaker.
 1988 NASA-Goddard Space Flight Center, Greenbelt MD.
 1988 Society of Surgical Chairman. Invited Speaker.
 1988 "Interaction between Sleep and the Circadian System", Society for Research on Biological Rhythms
 1988 Invited Symposium Speaker Association of Professional Sleep Societies, symposium chair
 1988 Medical Grand Rounds.
 1988 Duke University Medical Center, Durham NC
 1988 Clinical Chronobiology Conference. Invited Speaker.
 1988 Faculty Guest lecturer.
 1988 University of California Medical School, Davis, CA
 Between Invited Speaker.
 1988-1990 NASA Headquarters, Houston TX
 Between Invited Symposium Speaker
 1988-1990 Society for Neuroscience
 Between Symposium Speaker
 1988-1990 Academy of Behavioral Medicine Research
 1989 Invited Speaker.
 1989 NASA-Ames Research Center, Moffett Field, CA
 1989 Basic Sleep Research Panel. Invited Speaker.
 1989 Institute of Medicine, National Academy of Sciences, New York, NY
 1989 National Consensus Conference on Therapeutic Treatment of Sleep Disorders in Older People. Invited Speaker.
 1989 National Institute on Aging, Bethesda MD
 1989 "Correlations of Aging and Space: Effects on Biosystems". Invited speaker.
 1989 Joint Research Conference NASA, National Institute on Aging, and the Lew Evans Foundation
 1989 "Fatigue and Driver Alertness". Invited Speaker.
 1989 Federal Highway Administration, U.S. Department of Transportation
 1989 "Sleep and Driving Safety". Invited speaker.
 1989 National Press Club Conference
 1989 Society of Industrial and Occupational Hygienists Annual Meeting. Invited Speaker.
 1989 Invited Symposium Speaker.
 1989 American Association for the Advancement of Science
 1989 Medical Grand Rounds.
 1989 University of Texas Southwestern Medical School, Dallas TX
 1989 General Electric Company. Invited Speaker.
 1989 Smith College Colloquium. Invited Speaker.
 1989 Academic Practice Assembly, Administrators of Internal Medicine. Invited Speaker.
 1989 "Meet the Professor"
 1989 Association of Professional Sleep Societies
 1989 Postgraduate CME Course. Faculty Guest Lecturer.
 1989 Mayo Clinic Medical School, Rochester MN
 1989 Postgraduate CME Course. Faculty Guest Lecturer.
 1989 Presbyterian Hospital, University of Texas Southwestern Medical Center, Dallas TX
 1990 MacArthur Foundation Mental Health Research Network. Invited Speaker
 1990 NASA/National Science Foundation Conference on Antarctic Research. Invited Speaker.
 1990 Invited Speaker.

Rockefeller University, New York, NY.
 1990 Department of Pharmacology University of Chicago Colloquium. Invited Speaker.
 University of Illinois/Chicago Circle
 1990 Hypertension Symposium. Invited Speaker
 Marion Merrell Dow, Kansas City, MO
 1990 NASA Biomedical Research Program, Circadian Rhythms Workshop
 1990 Workshop on Circadian Rhythm Shifting, Medical Sciences Division. Invited Speaker.
 NASA-Johnson Space Center, Houston TX
 1990 Invited Speaker.
 American Psychiatric Association.
 1990 Medical Grand Rounds.
 University of Wisconsin-Madison Medical School, Madison WI
 1990 Endocrine Grand Rounds
 University of Wisconsin-Madison Medical School, Madison WI
 1990 Endocrine Grand Rounds
 University of Chicago, Chicago IL
 1990 Society of Research Administrators. Invited Speaker
 1990 Whitney Symposium on Science and Technology, General Electric Corporate Research
 and Development. Invited Speaker.
 1990 American Association of Homes for the Aging. Invited Speaker.
 1990 Session Chairman.
 Association of Professional Sleep Societies.
 1990 "Disorders of Circadian Function: Clinical Consequences and Treatment"; NIA/NIH
 Consensus Development Conference. Invited Speaker.
 1990 "Meet the Professor"
 Association of Professional Sleep Societies
 1991 National Advisory Council. Invited Speaker.
 National Institute on Aging, Bethesda MD
 1991 National Science Foundation Science and Technology Center Industrial Outreach
 Symposium. Invited Speaker.
 1991 3 teaching hospitals. Invited Speaker.
 1991 Invited Speaker.
 University of Virginia School of Medicine, Charlottesville VA
 1991 Invited Speaker.
 University of Chicago Pritzker School of Medicine, Chicago IL
 1991 Keynote Speaker.
 Central States Occupational Medical Association.
 1991 Invited Speaker
 Association of Polysomnographic Technologists.
 1991 Invited Speaker.
 University of Virginia, Charlottesville VA
 1991 Postgraduate CME Course. Faculty Guest Lecturer.
 Yale-New Haven Sleep Disorders Center
 Between Joint Conference. Invited Speaker.
 1991-1993 American Psychological Association, Brock University and National Institute of Mental
 Health
 Between Invited Speaker.
 1991-1993 Johns Hopkins University School of Medicine, Baltimore MD
 1992 National Advisory Council. Invited Speaker.
 National Institute of Neurological and Communicative Disorders and Stroke, Bethesda

MD

1992 Medical Grand Rounds.
Sinai Hospital of Baltimore, Baltimore, MD

1992 Invited speaker.
American Psychosomatic Society.

1992 “Human Phase-shifting and Entrainment”. Invited Speaker.
Society for Research on Biological Rhythms

1992 Invited Speaker.
National Institute for Brain Research.

1992 Invited Speaker.
Gordon Research Conference on Theoretical Biology and Biomathematics.

1992 Postgraduate CME Course. Invited Speaker.
Association of Professional Sleep Societies.

1993 Invited Speaker.
Inter-urban Clinical Club, Association of Professors of Medicine.

1993 Invited Speaker.
United States Army Research Institute of Environmental Medicine.
Life Sciences Division. Invited Speaker.

1993 NASA Johnson Space Center, Houston TX

1993 Invited Speaker.
Sleep Disorders Round Table, Smith-Kline-Beecham.

1993 “Circadian rhythms and sleep disorders: Role of melatonin” Workshop. Invited Speaker.
Institut de Recherches Internationales Servier

1993 “Sleeping Well: Overcoming Sleep Disorders” American Medical Association Educational
Briefing. Invited speaker.

1993 Invited Speaker.
Association of Professional Sleep Societies.

1993 Sleep Onset Mechanisms Conference. Invited Speaker.
American Psychological Association, Brock University and National Institute of Mental
Health, Division of Neuroscience and Behavioral Science

1993 National Science Foundation Center for Biological Timing Summer Course on Biological
Rhythms. Faculty Guest Lecturer.
University of Virginia, Charlottesville VA

1993 Faculty Guest Lecturer.
Gordon Research Conference on Chronobiology.

1993 Faculty Guest Lecturer.
Projects in Knowledge Faculty Training Program on Insomnia.

1993 Postgraduate CME Course “Controversies in Light Therapy”. Faculty Guest Lecturer.
Association of Professional Sleep Societies.

1994 Strategy Development Workshop on Sleep Education. Invited Speaker.
National Heart Lung and Blood Institute, Bethesda MD

1994 Workshop on Neural Basis of Psychopathology. Invited Speaker.
Division of Neuroscience and Behavioral Science, National Institute of Mental Health,
Bethesda MD

1994 Invited Speaker.
Rockefeller University, New York NY

1994 Scripps Clinic. Invited Speaker.

1994 Philips Forum. Invited Speaker.
Lighting Research Institute, Rensselaer Polytechnic Institute, Troy NY

1994 Invited Speaker.

1994 Interneuron Pharmaceuticals, Inc, Lexington MA
Invited Speaker.

1994 Alza Pharmaceutical, Mountain View CA
Workshop on Sleep Disorders,
Bristol Myers Squibb, New York NY

1994 “Circadian Control of REM Sleep”. Invited Speaker.
Society for Research on Biological Rhythms

1994 Symposium and workshop co-chair
Association of Professional Sleep Societies.

1994 AMDD Neurology Conference. Invited Speaker.
US Army Medical Department, Uniformed Services, University of the Health Sciences

1994 “Circadian Clocks and Their Adjustment”. Invited Speaker.
Ciba Foundation Symposium.

1994 Postgraduate CME Course on Sleep Disorders. Faculty Guest Lecturer.
Scripps Clinic.

1994 Postgraduate CME Course “Shift Work: Health Effects and Coping Strategies”. Faculty
Guest Lecturer.
American College of Occupational and Environmental Medicine, Elk Grove Village IL

Between 1994-1996 Invited Speaker.
Woods Hole Marine Biological Laboratory Lecture Series

Between 1994-1996 Invited Speaker. Workshop on Melatonin and Sleep
National Institute on Aging, Bethesda MD

Between 1994-1996 Invited Speaker.
American Thoracic Society

Between 1994-1996 Postgraduate CME Course
American Clinical Neurophysiology Society

Between 1994-1996 Postgraduate CME Course
CME, Inc.

1995 “Managing Fatigue in Transportation: Promoting Safety and Productivity” Multimodal
Educational Symposium. Invited speaker.
National Transportation Safety Board and NASA Ames Research Center

1995 Neurology Grand Rounds
Emory University School of Medicine, Atlanta GA

1995 Invited Speaker.
Air Force Office of Scientific Research Headquarters

1995 Invited Speaker.
Merck Pharmaceutical

1995 Invited Speaker.
American Physiological Society, Dartmouth

1995 Invited Speaker.
Aerospace Medical Association

1995 Invited Speaker.
National Foundation for Brain Research

1995 Invited Speaker.
New England Science Writers Association

1995 Invited Speaker.
Association of Professional Sleep Societies

1995 “Meet the Professor”
Association of Professional Sleep Societies

Between NASA Workshop on Aging and Spaceflight. Invited Speaker.

1997-2001 National Institute on Aging, Bethesda MD
Between Plenary session speaker.

1997-2001 International Conference on Managing Fatigue in Transportation
Between Systems Physiology Workshop. Invited Speaker.

1997-2001 National Research Council, National Academy of Sciences
Between Invited Speaker.

1997-2001 National Space Biomedical Research Institute
Between Invited Speaker.

1997-2001 Federal Transit Administration, Department of Transportation
Between Invited Speaker.

1997-2001 Johnson Space Center, National Aeronautics and Space Administration
Between Invited Speaker.

1997-2001 Charleston Air Force Base, Air Force Office of Scientific Research
Between Invited Speaker (2 symposia)

1997-2001 Society for Research on Biological Rhythms
Between Invited Speaker.

1997-2001 Recent Progress in Hormone Research Conference, The Endocrine Society
Between Invited Speaker.

1997-2001 Cephalon, Inc.
Between Workshop Speaker.

1997-2001 American Physiological Society
Between Symposium Speaker.

1997-2001 Society for Neuroscience
Between Workshop Speaker.

1997-2001 Society for Research on Biological Rhythms
Between Workshop Speaker.

1997-2001 American Academy of Sleep Medicine
Between Keynote Speaker.

1997-2001 Committee of Interns and Residents
Between Invited Speaker.

1997-2001 Biological Effects of Light Symposium
Between Faculty Guest Lecturer. Symposium chair

1997-2001 Gordon Conference on Chronobiology
Between Faculty Guest Lecturer.

1997-2001 Gordon Conference on Pineal Physiology
Between Postgraduate CME Course. Faculty Guest Lecturer.

1997-2001 American Medical Association, American Academy of Sleep Medicine.
Between Medicine Conference on Sleep, Fatigue and Medical Training. Faculty Guest Lecturer.

1997-2001 Virginia
Between Keynote speaker

1997-2001 Association of Professional Sleep Societies
Between Faculty Guest Lecturer. "Meet the Professor"

1997-2001 Associated Professional Sleep Societies
Between Postgraduate CME Course. Faculty Guest Lecturer and course organizer.

1997-2001 Associated Professional Sleep Societies
Between Keynote Speaker.

2002-2008 Society for Research on Biological Rhythms Annual Meeting
Between Invited Speaker.

2002-2008 Association for Patient Oriented Research
Between Neurology Grand Rounds

2002-2008 Johns Hopkins University School of Medicine, Baltimore, MD
Between Invited Speaker.

2002-2008 Vanda Pharmaceuticals, Rockville, MD
Between Invited Speaker.

2002-2008 Association of American Medical Colleges, Washington, DC
Between Invited Speaker.

2002-2008 Accreditation Council of Graduate Medical Education Annual Education Conference,
Chicago IL
Between Invited Speaker.

2002-2008 Institute of Life Sciences: Sleep, Energy and Health Symposium, Washington, DC
Between Invited Speaker.

2002-2008 Institute for Systems Biology, Seattle WA
Between Invited Speaker.

2002-2008 Neurocrine Biosciences
Between Faculty guest lecturer

2002-2008 Neurocrine, San Diego CA
Between Trainee Day Speaker.

2002-2008 Association of Professional Sleep Societies
Between Postgraduate CME "Year in Review"
Lecturer "Insomnia and Beyond"
Lecturer "Shift Work Sleep Disorder"

2002-2008 Associated Professional Sleep Societies Annual Meeting
2004 Invited Speaker.
Bioterrorism and Trauma Conference, University of Maryland, Baltimore MD

2004 Invited Speaker. National Sleep Conference
National Center for Sleep Disorders research, National Heart, Lung and Blood Institute,
NIH, Bethesda, MD

2005 Semi-Annual Joint Grand Rounds in Surgery and Anesthesia and Pfizer Lecturer in Sleep
University of Michigan Health Systems, Ann Arbor MI

2005 Invited Symposium Speaker.
Society of Critical Care Medicine, Phoenix, AZ

2005 Invited Speaker, Trainee Symposium.
Sleep Research Society, Denver, CO

2005 Keynote Speaker.
Annual Meeting, Committee of Interns & Residents, Washington, DC

2005 Gordon Wilson Lecture: "Work Hours, Sleep And Patient Safety In Residency Training"
Annual Meeting, American Clinical and Climatological Association

2006 Invited Speaker.
American Academy of Allergy, Asthma and Immunology Program Directors' Winter
Meeting

2006 Symposium Speaker
Annual Meeting, Association of University Anesthesiologists, Tucson AZ

2006 Clinical Grand Rounds
National Institutes of Health, Bethesda MD

2006 Psychiatry Grand Rounds.
Dartmouth Medical School, Lebanon, NH

2006 Beckwith Family Lecture. Medical Grand Rounds.
Brown University, Providence, Rhode Island

2006 Faculty Guest Lecturer.
University of Virginia Medical School

2006 Faculty Guest Lecturer.
University of Pennsylvania, PA

2006 Grand Rounds.
National Institutes of Health, Bethesda MD

2006 Faculty Guest Lecturer.
Center for Patient Safety Research and Practice, Executive Council Meeting, Boston, MA

2007 “Sleep Deprivation and Fire/Emergency Services— Just How Dangerous Is It?” Invited Speaker
U.S. Fire Administration (USFA) Executive Fire Officer Program Graduate Symposium, Emmitsburg, MD

2007 Dorcas Cummings Lecture “Work Hours, Sleep and Safety: Physician Heal Thyself”
Invited Symposium Speaker “Human Circadian Rhythms”
72nd Symposium: Clocks and Rhythms, Cold Spring Harbor Laboratory, NY

2007 “Effects of Extended Work Hours on Intern Safety and Health and Medical Mistakes”.
Invited Speaker
Office of the Director Seminar Series, National Institute for Occupational Safety and Health

2007 WALIS Invited lecture: “Application of Sleep Science and Circadian Biology to Clinical Medicine”.
National Institutes of Health, Bethesda MD

2007 “Impact of Sleep Deprivation on Clinical Care”
Duke University Medical Center, NC

2007 Invited Panelist “The Basics. Science & Society Issues. What we think we know about sleep. A clinical primer” and “Influences of Sleep Behavior - from Genes to Environment. Functional Genomics. Drugs. Light. Sleep apnea”
The Science Network at the Salk Institute, CA

2007 Human Research Program Investigators' Workshop
NASA, League City TX

2007 “Circadian Rhythms, Sleep and Work Hours: Ethical Implications for Health Care Workers”
Morehouse School of Medicine, Atlanta, GA

2007 “Circadian rhythm sleep disorders”
Neurobiology of Disease Workshop, Society for Neuroscience, CA

2007 Invited Speaker, Trainee Symposium.
Sleep Research Society, Minneapolis, MN

2008 Invited Symposium Speaker: “Human Circadian Rhythms”
and “Meet the Professor”
Society for Research on Biological Rhythms Annual Meeting, Destin FL

2008 Postgraduate Course: “Creating a Division of Sleep Medicine”
Trainee day speaker: “Public Health and Sleep”
Invited lecturer: “Sleep and circadian rhythms in humans: Tales of translation from the lab to practice”
Association of Professional Sleep Societies Annual Meeting, Baltimore MD

2008 Keynote Speaker “Sleep and Public Policy”
9th Annual Upper Midwest Sleep Society, University of Wisconsin, Madison WI

2008 Invited Speaker: “Genetic vulnerability to neurocognitive dysfunction from sleep loss: An ethical dilemma for the medical profession”
American Clinical and Climatological Association Annual Meeting, Ponte Verde FL

2008 Invited Speaker: “Duty Hours and Sleep Deprivation: When Will the Residents Learn?”
Association of Professors of Medicine Fall Symposium, Florida

2009 Invited Speaker: “Work, Sleep Hours and Patient Safety”
Society for Obstetric Anesthesia and Perinatology, 41st Annual Meeting, Washington DC

2009 Invited Speaker Trainee Symposium “Public Health and Sleep”
Association of Professional Sleep Societies Annual Meeting, Seattle WA

2009 Medicine Grand Rounds
University of Washington, Seattle, WA

2009 Guest Faculty: “Medical and Genetic Differences in the Adverse Impact of Sleep Loss on
Performance: Ethical Considerations for the Medical Profession”
GME Institutional Lecture Series, University of Virginia, Charlottesville, VA

2010 Invited Speaker: “The human circadian rhythm”
Nocturnal Frontal Lobe Epilepsy [sponsored by Alliance for Epilepsy Research and the
Office of Rare Diseases Research at the NIH] Sanibel Island, FL

2010 Keynote address: “Neurobiology of the Human Circadian Pacemaker of its Role in the
Regulation of Sleep”
MSTP program (MD-PhD), Duke University School of Medicine, Durham, NC

2010 Organizer & Speaker: “Circadian Rhythm Disorders”
Circadian Rhythms and Metabolic Disease workshop, NIDDK/NIH, Bethesda, MD

2010 “Meet the Professor”
Society for Research on Biological Rhythms Annual Meeting, Destin FL

2010 Meet the Professor: “Resetting the human circadian pacemaker with light”
Association of Professional Sleep Societies Annual Meeting, San Antonio, TX

2010 Invited Speaker: “Regulation of sleep in humans”
Sackler Colloquium - Quantification of Behavior, National Academy of Sciences,
Washington, DC

2010 Conference Co-chair “Shift work and sleep: Optimizing health, safety and performance”
American College of Occupational and Environmental Medicine (ACOEM) and NIH,
Arlington, VA [Sponsored by Cephalon, Inc.]

2011 Invited Speaker “Light, Sleep, and Circadian Regulation of the Pineal Hormone
Melatonin”
Endocrine Research Seminar, University of Chicago, Chicago, IL

2011 Invited Speaker “Resident Physician Work Hours, Patient Safety, and Occupational
Health: Striking a Balance”
Medicine Grand Rounds, University of Chicago, Chicago, IL

2011 Conference Co-chair “Sleep Health and Safety” and Speaker
National Sleep Foundation (NSF), Washington DC

2011 Keynote Speaker “The Impact of Sleep Deprivation & Shift Work on Medical Errors”
North East Sleep Society, Newport RI

2011 Session Chair “Circadian Adaptation to Martian Sol Panel” and Invited Speaker “Near-24-
hour Intrinsic Period of the Human Circadian Pacemaker: Challenge for Adaptation to the
Martian Sol”
18th IAA Humans in Space Symposium, Houston TX

2011 Invited Neonatology Lecture “Circadian Rhythms, Development and Neonatal Intensive
Care”
University of Colorado, Denver CO

2011 Pediatric Grand Rounds “Optimizing Physician Work Hours and Sleep to Improve Patient
Safety and Occupational Health”
University of Colorado, Denver CO

2011 Session Chair “Sleep and Memory in Normal Aging” and Invited Speaker “Age-related
changes in sleep organization”
Sleep in Aging and Dementias Meeting, NIA, Bethesda MD

2011 Invited Program Speaker “Changing the game: Using circadian bio-markers in clinical medicine”
Minneapolis, MN [Sponsored by Philips/Respironics]

2011 Invited Speaker, Discussion Panel “Sleep Science and the Law: The Legal State of Mind of Drowsy and Sleeping Parties in Legal Proceedings”
Association of Professional Sleep Societies Annual Meeting, Minneapolis MN

2011 Chair, Discussion Panel “The National Institutes of Health Sleep Research Plan (2011)”
Association of Professional Sleep Societies Annual Meeting, Minneapolis MN

2011 Invited Speaker, Advisory Committee” Addressing Obstructive Sleep Apnea In CMV Drivers”
Federal Motor Carrier Safety Administration, Alexandria VA

2012 Invited Speaker, Sleeplessness Panel
WME Entertainment, San Diego CA

2012 Invited Speaker, Ethics Debate: Sleep Deprived Surgeons Should Not be Allowed to Operate Without Patients’ Consent
Society of Thoracic Surgeons, Fort Lauderdale FL

2012 Invited Speaker; Sleep Health & Safety Conference
National Sleep Foundation, Washington DC

2012 Invited Speaker
NSBRI Board of Directors, Houston TX

2012 Panelist “The City Dark”
AAAS, New York City, NY

2012 Meet the Professor
Society for Research on Biological Rhythms, Destin FL

2012 Speaker, Discussion Panel “Measuring Sleepiness in Drivers: The Challenges and Controversies”
Association of Professional Sleep Societies Annual Meeting, Boston MA

2012 Invited Speaker “Body Mass Index is an Effective Measure for Occupational Screening of Employees at High Risk for Moderate to Severe Obstructive Sleep Apnea: Implications for DOT Commercial Driver Medical Examinations”
Association of Professional Sleep Societies Annual Meeting, Boston MA

2012 Invited Speaker “Sleepless in Seattle (and Elsewhere): Women and the Need for Quality Sleep”
AWHONN (Association of Women's Health, Obstetric and Neonatal Nurses), Annual Meeting, National Harbor MD

2013 Invited Speaker “Light as a countermeasure for circadian rhythms, sleep, alertness, performance, mood, endocrine and other physiologic factors” and “Effects of sleep and sleep deprivation on brain and behavior”
NSBRI inter-team meeting “Effects of Long Duration Spaceflight on Brain and Behavior”, Houston TX

2013 Invited Speaker “Prevalence and Consequences of Sleep Disorders among American Law Enforcement Officers”
National Sleep Foundation Sleep Health & Safety Conference, Washington DC

2013 Invited Speaker “The Sleep Gap: Why is it growing?”
Science in Medicine Annual Lecturer, University of Washington, Seattle WA

2013 Faculty Speaker – Postgraduate Course “Basic and Translational Circadian Science for the Clinician and Trainee”
Association of Professional Sleep Societies Annual Meeting, Baltimore MD

2013 Speaker – Discussion Group “Advancing Sleep and Circadian Rhythms Research”
Association of Professional Sleep Societies Annual Meeting, Baltimore MD

- 2013 Chair and Speaker “State of the Art Symposium on Drowsy Driving: Impact of Sleep Deficiency on Real Motor Vehicle Driving Performance and Perception of Drowsiness”
Association of Professional Sleep Societies Annual Meeting, Baltimore MD
- 2013 Invited Speaker “Genetics of Neurobehavioral Functions during the 12-Month ISS Mission (ISS12): Capitalizing on Discoveries in Circadian, Sleep and Stress Neurobiology”
NASA, Houston TX
- 2013 Invited Special Lecture “Interacting Influence of Sleep and Circadian Clocks on Human Physiology and Cognitive Performance”
Society for Neuroscience Annual Conference, San Diego CA
- 2014 Faculty Speaker - Emerging Clinical and Business Trends in Sleep Medicine Course.
“Sleep and Anesthesia: Are They One in the Same?” and “The Role of Circadian Rhythms in Pilots Who Navigate Across Time Zones”
American Academy of Sleep Medicine, Phoenix AZ
- 2014 Invited Speaker “Shift Work and Its Effects on Healthcare Workers”
Symposium entitled ‘The Impact of Circadian Disruption on Shift Workers: Healthcare and Disease’, Montefiore Medical Center, Bronx NY
- 2014 Invited Speaker – Workshop “Funding outside the NIH”
Association of Professional Sleep Societies Annual Meeting, Minneapolis MN
- 2014 Speaker – Discussion Group “Stone soup: Leveraging research resources and opportunities”
Association of Professional Sleep Societies Annual Meeting, Minneapolis MN
- 2014 Meet the Professor
Association of Professional Sleep Societies Annual Meeting, Minneapolis MN
- 2014 Speaker – Workshop “Clocks in the Clinic: Should we have Chronobiology Clinics?”
Society for Research on Biological Rhythms Biennial Meeting, Big Sky MT
- 2014 Meet the Professor
Society for Research on Biological Rhythms Biennial Meeting, Big Sky MT
- 2014 Invited Presenter “Sleep and Circadian Rhythms in Spaceflight - a review”
Special Workshop on ‘Sleep on Earth and in Space: Risk Factors, Health & Performance Outcomes, and Countermeasures’, NASA/NSBRI, Houston TX
- 2014 Invited Speaker “Sleep, Health and Safety of First Responders”
National Sleep Foundation Sleep Health & Safety Conference, Washington DC
- 2015 Advocate, Sleep Leadership Summit
National Sleep Foundation, Washington DC
- 2015 Invited Speaker “Teasing apart the impact of prior exposure to recurrent circadian disruption and chronic sleep restriction on pancreatic β -cell responsiveness”
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Workshop on “Impact of Sleep and Circadian Disruption on Energy Balance and Diabetes”, Bethesda MD
- 2015 Invited Faculty “Sleep, Circadian Rhythms, and Performance”
Stanford University School of Medicine/National Sleep Foundation, CME course
“Managing Sleep Health in the Primary Care Setting”, Stanford CA
- 2015 Speaker “Irregular Sleep In College Students: Consequences For Sleep Consolidation Circadian Rhythms And Performance”
Association of Professional Sleep Societies Annual Meeting, Seattle WA
- 2015 Invited Speaker “The A to ZZZs of Sleep”
Robb Report Health and Wellness Summit, Park City UT
- 2015 Invited Panelist “Sleep for Performance, Safety and Health”
Office of Naval Research workshop ‘Restorative Sleep’, Arlington VA
- 2015 Invited Speaker “Interactive Effects of Sleep and Circadian Rhythms on the Performance,

Safety and Health: Implications for the Military”
The WRAIR Distinguished Speakers Seminar Program, Walter Reed army Institute of
Research, Silver Spring MD

2015 Invited Speaker “Circadian Rhythm Disorders”
Vermont and New Hampshire Society for Respiratory Care, Annual Meeting, Meredith
NH

2015 Invited Panelist “Digital Media and Psychological/Emotional/Physical Development in
Adolescents”
Arthur M. Sackler Colloquium Digital Media and Developing Minds, Irvine CA

2015 Invited Speaker “Balancing the Needs for Research and Action”
National Highway Traffic Safety Administration (NHTSA) Drowsy Driving Forum,
Washington DC

2015 Invited Speaker “Drowsy Driving Overview: Data, Measurement & Contributing Factors”
Sleep Health and Safety Conference, National Sleep Foundation (NSF), Washington DC

2015 Invited Speaker “Impact of Circadian Rhythms on Sleep and Sleep Disorders”
Sleep Summit: Advanced Topics in Narcolepsy and OSA, Sponsored by Jazz
Pharmaceuticals, Palo Alto CA

2016 Keynote Speaker “Sleep Deficiency and Motor Vehicle Crashes”
Maryland Sleep Society Seventh Annual Scientific Meeting, Baltimore MD

2016 Speaker – Symposium “Effects of light on human circadian rhythms”
Society for Research on Biological Rhythms Biennial Meeting, Tampa FL

2016 Speaker “Brigham and Women's Hospital Presents: Living Better Longer - The Science
Behind Healthy Aging”
BWH Spotlight Health at Aspen Ideas Festival, Aspen CO

2016 Invited Speaker “The Secrets of Sleep”
Robb Report Health and Wellness Summit, Park City UT

2016 Invited Panelist “How Sleep Can Improve Your Bottom Line”
National Sleep Foundation Sleep Works Summit, Washington DC

2017 Invited Panelist “Mini Symposium in Circadian Rhythms”
Hawaii Sleep Health and Wellness Foundation's Conference

2017 Invited Speaker “Circadian Clocks, Sleep and Health”
UC San Diego Circadian Biology Symposium, San Diego CA

2017 Invited Speaker “Sleep Regulation in Humans”
Invited Speaker University of Washington Graduate Program in Neuroscience, Seattle WA

2017 Invited Speaker “Deficient Sleep in Teens: The Consequences. Impact on Health”
Adolescent Sleep, Health, and School Start Times, Washington DC

2017 Invited Speaker “OSA and Trains, Planes and Automobiles”
American Academy of Dental Sleep Medicine Annual Meeting, Boston MA

2017 Speaker “The Global Council on Brain Health Consensus Statement and
Recommendations for Maintaining Healthy Sleep for Brain Health”
Association of Professional Sleep Societies Annual Meeting, Boston MA

2017 Invited Speaker “Chronobiology, Circadian Rhythms, and Sleep: Clinical and Advanced
Translational FindingsDoD State of the Science Summit Pathophysiology of PTSD:
Rethinking Drug Targets

2017 Speaker “Brigham and Women's Hospital Presents: Vulnerabilities and Resiliency across
the Life Span: The Brain”
BWH Spotlight Health at Aspen Ideas Festival, Aspen CO

2017 Invited Speaker “Sleep and Fatigue Effect on Performance”
Special Operations Forces (SOF) Performance Nutrition Summit, Fort Bragg NC

2017 Invited Speaker for 4 talks:

- 1: Sleep Medications and Athletic Performance
 - 2: Circadian Effect on Sports Performance
 - 3: Sleep and Fatigue Management in the Workplace: Jet lag & Travel Fatigue for Business Management
 - 4: Panel Discussion: Going Without Sleep is Nothing to Brag About
- Alaska Sleep Conference, Anchorage AK *sponsored by Ganesco*
- 2017 Invited Speaker “Fatigue in our heroes: Addressing fatigue risk in first responders story”
National Safety Council Annual Meeting, Indianapolis IN
- 2018 Invited Speaker “Circadian clock regulation of sleep and wakefulness in humans”
Salk/Foundation Ipsen/Science Symposium on Biological Complexity: Biology of Time (Circadian, Lunar and Seasonal Rhythms), La Jolla CA
- 2018 Invited speaker for colloquium on “Sleep, Chronic Fatigue and Autoimmune Disease”
AARDA (American Autoimmune Related Disease Association), Washington DC
- 2018 Invited Speaker for IES 2018 Research Symposium Light + Human Health
IES (Illuminating Engineering Society), Atlanta GA
- 2018 Invited Speaker “Sleep and Circadian Rhythms: Impact on Performance, Health and Safety of U.S. Navy and Marine Corps Personnel”
Office of Naval Research (ONR) Distinguished Lecture Series, Arlington VA
- 2018 Invited Speaker “Guidelines of OSA Management in Commercial Motor Vehicle Operators”
American Academy of Dental Sleep Medicine Annual Meeting, Baltimore MD
- 2018 Speaker “Is sleeping long bad for you”
Association of Professional Sleep Societies Annual Meeting, Baltimore MD
- 2018 Invited Speaker “Sleep Timing Variability Consensus Panel”
National Sleep Foundation Sleep Health Forum, Association of Professional Sleep Societies Annual Meeting, Baltimore MD
- 2018 Invited Speaker “The Sleep Deprived Brain’s Influence on Aging”
6th Annual AspenBrainLab, Aspen Brain Institute, Aspen CO
- 2018 Expert Panelist for Drowsy Driving Attitudes, Knowledge, and Behavior Project.
NHTSA, Washington DC
- 2018 Invited Panel Speaker, SRS Regulatory Meeting

International

- 1976 Invited Speaker.
Max-Planck-Institut für Verhaltensphysiologie, Erling-Andechs, Germany
- Between 1976-1980 Invited Speaker.
3rd International Congress of Sleep Research, Tokyo
- Between 1981-1984 Invited Speaker.
International Union of Physiological Sciences, Budapest
- Between 1981-1984 Invited Speaker.
International Workshop on Sleep/wake disorders: natural history, epidemiology and long-term evolution, Ravenna, Italy
- 1984 Invited Speaker. Symposium on Biological Rhythms.
International Congress on Neuroreceptor Mechanisms in Human Disease, Fondazione Internazionale Menarini, Florence, Italy
- 1986 “Effects of automation on operator performance”. Invited Speaker
Commission of the European Communities, Université René Descartes, Paris, France
- 1987 Invited Speaker.
5th International Congress of Sleep Research, Copenhagen, Denmark

1987 Invited Speaker.
German Institute for Aerospace Medicine, Köln, Germany

1987 Invited Speaker.
International Conference on Chronobiology, Leiden, Netherlands

1987 Invited Speaker.
NATO Defense Research Group Seminar on Sleep and its Implications for the Military,
Lyon, France

1988 Invited Speaker.
European Congress of Sleep Research, Jerusalem

1988 Invited Speaker.
Workshop on Polyphasic and Ultrashort Sleep-Wake Patterns, Tuscany, Italy

1988 Invited Speaker.
Institute of Pharmacology, University of Zurich, Zurich, Switzerland

1988 Invited Speaker.
Tenth International Symposium, Center of Research on Neurological Sciences, University
of Montreal, Quebec, Canada

1989 “Mechanisms in the timing of sleep: Consequences for depression research”. Invited
Speaker.
University of Groningen 375th Anniversary Symposium, Netherlands

1989 “Cardiovascular and Nervous System Effects of Ovarian Secretions”. Invited Speaker.
Serono Symposium, Dubrovnik, Croatia

1989 Invited Speaker.
2nd Milano International Symposium on Sleep, Milan, Italy

1989-1990 Faculty research sponsor; Research Elective 1 medical student; ~15 hours/year
Philipps University, Marburg, Germany

1992-1994 Faculty research sponsor; Research Elective 1 medical student; ~15 hours/year
Medical School of the Technical University of Munich, Munich, Germany

1998-2003 Co-Mentor, Doctoral Student in Pharmacology
Swiss Federal Institute of Technology, Zurich, Switzerland

1990 Invited Speaker
17th Congress, Collegium Internationale Neuro-Psychopharmacologicum, Kyoto, Japan

1990 Invited Speaker
American Society for Photobiology, Vancouver, British Columbia, Canada

1990 Invited Speaker
Workshop on Psychophysiological Measures in Transport Operations, Commission of the
European Communities, Paris, France

1990 Invited Speaker
Japan Institute for the Science of Labor, Tokyo, Japan

1990 Invited Speaker
National Institute of Health Services and the Central Health Institution, Tokyo, Japan

1991 Invited Symposium Speaker/Co-Chairperson: “Endocrine and Metabolic Correlates of
Sleep and Wakefulness in Humans”
Invited Workshop Speaker: “Constant Routines”
World Federation of Sleep Research Societies, Cannes, France

1991 Invited Speaker
Study Group on Circadian Rhythms, Fondation pour L'Etude du Systeme Nerveux et
Peripherique, Geneva, Switzerland

1991 Invited Speaker
Gordon Research Conference on Chronobiology, Irsee, Germany

1991 Invited Speaker

1992 Workshop on Concepts and Models of Sleep Regulation, Zurich, Switzerland
Keynote Speaker
International Brain Research Organization-Suisse, Zurich, Switzerland

1994 Invited Speaker
International Conference on Work Hours, Sleepiness and Accidents Karolinska Institute,
Stockholm, Sweden.

Between
1994-1996 Invited Speaker
Ciba Foundation Symposium, London, United Kingdom

1995 Invited Speaker
World Federation of Sleep Research Societies, Bahamas

1996 Invited Speaker
Japanese Society for Sleep Research, Sapporo, Japan

1996 Invited Speaker
International Workshop on Circadian Light Reception and Regulation, Lyon, France

Between
1997-2001 Invited Speaker
International Conference on Managing Fatigue in Transportation, Karolinska Institute,
Stockholm, Sweden

Between
1997-2001 Workshop chair and Trainee Day speaker
Third International Congress, World Federation of Sleep Research Societies, Dresden,
FRG

2002 Symposium co-chair and Invited Speaker
American Society for Photobiology, Quebec City, Canada

Between
2002-2008 Invited Speaker
1st International Conference on Circadian Rhythms, Sleep and Cognition, Toronto, Canada

2003 Plenary Speaker
World Congress on Chronobiology, Sapporo, Japan

2003 Invited Speaker. Autumn School "Circadian Rhythms"
Institute of Biology, Humboldt-University, Charité Hospital, Berlin, Germany

2003 Invited Speaker
British Medical Association, London, United Kingdom

2003 Invited Speaker
Gordon Research Conference on Chronobiology, Barga, Italy

2003 Invited Speaker
Launch Event, Surrey Sleep Research Centre, Guildford, England

2004 Invited Speaker
Spark Workshop, Unilever, United Kingdom

2004 Invited Speaker
2nd Annual Sleep Disorders Forum, Sanofi Synthelabo, Paris, France

2005 Plenary Address
X International Congress, Brazilian Sleep Research Society, Curitiba, Brazil

2005 Plenary Speaker
New Zealand Resident Doctors Association Professional Conference on Safer Working
Hours in Medicine, Auckland, New Zealand

2006 Distinguished Leader in Medicine Lecture "Work Hours, Health and Safety in the Medical
Profession"
Dalhousie University, Halifax, Canada

2007 Invited Speaker "The neurobiology of the human circadian pacemaker, and medical
education in the United States"
Osaka University, Japan

- 2007 Invited Speaker ““Neurobiology of the human circadian pacemaker and Sleep Regulation” & “Establishing Divisions of Sleep Medicine at the Harvard Medical School: Fostering education, patient care and research”
University of Tsukuba, Japan
- 2007 Invited Speaker. “Recent advances of sleep medicine for work safety”
Tokyo Electric Power Company, Japan
- 2007 Invited Speaker “Clinical trial of the efficacy of Modafinil in the treatment of shift work sleep disorder”
Japanese Sleep Research Society, Japan
- 2007 Invited Speaker “Sleep loss and sleep disorders: Public health impact”
Monash University, Melbourne, Australia
- 2007 Invited Speaker “Safe working hours and Fatigue”
and Panelist “Different perspectives on the health industry workforce”
University of Sydney, Australia
- 2007 Invited Speaker “Influence of Internal Circadian Phase on Excessive Sleepiness and Behavioral Alertness in Patients with Shift-Work Sleep Disorder (SWSD)”
18th International Symposium on Shiftwork and Working Time, Yeppoon, Australia
- 2007 Plenary Speaker “Sleep Medicine in the 21st Century”
5th Congress of the World Federation of Sleep Research and Sleep Medicine Societies, Cairns, Australia
- 2007 Invited Speaker “Sleep Medicine and Education”
University of Zurich, Switzerland
- 2007 Invited Speaker “24 Hour Society and Work; an Update on Better Shift Work”
Harvard Medical School Dubai Center Institute for Postgraduate Education & Research, Dubai, UAE
- 2008 Invited Speaker “Sleep, work, productivity and safety”
6th International Sleep Disorders Forum, Toronto, Canada
- 2010 Symposium Co-chair “Sleep in unusual and extreme environments”
20th Meeting of the European Sleep Research Society, Lisbon, Portugal
- 2010 Invited Speaker “Sleep deficiency, drowsiness and circadian dysregulation: assessment, consequences and treatment approaches”
Decade of the Mind Conference, Singapore
- 2010 Invited Speaker
Astronaut Center of China, Beijing, China
- 2011 Invited Speaker “Regulation of sleepiness: the importance of light, circadian rhythms, and homeostasis”
Stress Research Institute, University of Stockholm: Working Time Society; Satellite Symposium ‘The Sleepy Brain’, Stockholm, Sweden
- 2011 Invited Speaker “Fatigue risk management in transport”
Working Time Society; 20th International Symposium on Shiftwork and Working Time
- 2011 Keynote Speaker “Sleep and Work Schedules in Modern Society”
World Association of Sleep Medicine, Quebec City, Canada
- 2011 Invited Educational Lecture “Circadian Rhythms, Human, Sleep & Wake”
6th World Congress of the World Sleep Federation, Kyoto, Japan
- 2011 Invited Speaker “Sleep in Space”
JAXA Symposium, Kyoto, Japan
- 2011 Invited Speaker
Satellite Meeting ‘Translational Sleep Research - From animal research to human study’, Kyoto, Japan
- 2011 Invited Public Lecture

- 2011 Kyoto, Japan
Invited Speaker
International Symposium on Photonic Bioimaging and Satellite Symposium of WorldSleep
2011 on Human Circadian Clock: the 50th anniversary of temporal isolation study,
Sapporo, Japan
- 2011 Invited Speaker
Board of Directors Meeting, Canadian Association of Internes & Residents, Ottawa ON
(remote presentation)
- 2012 Invited Speaker “Human circadian rhythms: Impact on sleep and cognition”
Seminar in Neuroscience, Biocentre in Basel, Basel, Switzerland
- 2012 Invited Speaker “Shift work, circadian rhythms, health and performance” & “Work hours,
sleep and patient safety in medicine”
International Postgraduate Course “The Risk of Fatigue”, University Hospital, Basel,
Switzerland
- 2013 Invited Speaker
“Non-visual Forum, University of Manchester, Manchester, United Kingdom
- 2013 Invited Speaker “Pathophysiology of Drowsy Driving: Impact of Circadian Rhythms,
Sleep Deficiency and Shift Work”
Excessive Daytime Sleepiness, Work and Road Safety Conference, University of Bologna,
Bologna, Italy
- 2013 Invited Speaker – Special Lecture “Role of Sleep Medicine and Chronobiology for
Optimizing Productivity, Safety and Health in the Workplace”
86th Annual Meeting of the Japan Society for Occupational Health, Matsuyama City,
Japan (remote presentation)
- 2014 Discussion Leader in three sessions (1) ‘Rethinking Health’, (2) ‘Do-it-yourself Health’
and (3) ‘From Hyper to Healthy’
World Economic Forum, Annual Meeting 2014, Davos-Klosters, Switzerland
- 2014 Invited Lecture
University of Bordeaux, Bordeaux, France.
- 2016 Invited Speaker
Zurich Global Risk Management Summit, Cannes, France
- 2016 Invited Lecture “Non-24-Hour Disorder: History, Pathophysiology and Clinical
Assessment”
Annual Congress of the German Sleep Society (DGSM), Dresden Germany
- 2017 Plenary Speaker, “Impact of Artificial Light on Entrainment of the Human Circadian”
Annual Congress, European Biological Rhythms Society (EBRS), Amsterdam Netherlands
- 2018 Keynote Lecture “Sleep and Health: A Clinical Research Priority”
Zurich Sleep Medicine Symposium 2018 / International Symposium of the CRPP Sleep &
Health, University of Zürich, Zürich, Germany
- 2018 Invited Faculty
“The Role of Circadian Biology in Preventing and Treating Pathology”
Ludwig-Maximilians-University of Munich, Germany

Report of Clinical Activities and Innovations

Current Licensure and Certification

- 1982- Diplomate, American Board of Sleep Medicine

Report of Technological and Other Scientific Innovations

Assessment and Modification of a Subject's Endogenous Circadian Cycle.	Czeisler CA , Kronauer RE, Allan JS. Assignee: Brigham and Women's Hospital. Patent Number 612182. Issue Date: 10/25/91; Country: Australia.
Test for Evaluation of Visual Functioning in Visually Impaired Subjects.	Czeisler CA , Martens H, Shanahan TL. Assignee: Brigham and Women's Hospital. Patent Number 5,146,927. Issue Date: 9/15/92; Country: U.S.
Assessment and Modification of a Subject's Endogenous Circadian Cycle.	Czeisler CA , Kronauer RE, Allan JS. Assignee: Brigham and Women's Hospital. Patent Number 5,163,426. Issue Date: 11/17/92; Country: U.S.
Assessment and Modification of Endogenous Circadian Phase and Amplitude.	Czeisler CA , Kronauer RE, Allan JS. Assignee: Brigham and Women's Hospital. Patent Number 5,167,228. Issue Date: 12/1/92; Country: U.S.
Assessment and Modification of Circadian Phase and Amplitude.	Czeisler CA , Kronauer RE, Allan JS. Assignee: Brigham and Women's Hospital. Patent Number 5,176,133. Issue Date: 1/5/93; Country: U.S.
Assessment and Modification of a Subject's Endogenous Circadian Cycle.	Czeisler CA , Kronauer RE, Allan JS. Assignee: Brigham and Women's Hospital. Patent Number 1327630. Issue Date: 3/8/94; Country: Canada.
Assessment and Modification of a Human Subject's Circadian Cycle.	Czeisler CA , Kronauer RE, Allan JS. Assignee: Brigham and Women's Hospital. Patent Number 5,304,212. Issue Date: 4/19/94; Country: U.S.
Apparatus for Producing and Delivering High-Intensity Light to a Subject.	Czeisler CA , Kronauer RE, Kyricos CJ. Assignee: Brigham and Women's Hospital and Light Sciences, Inc. Patent Number 5,503,637. Issue Date: 4/2/96; Country: U.S.
Intermittent Use of Bright Light to Modify the Circadian Phase.	Czeisler CA , Kronauer RE. Assignee: Brigham and Women's Hospital. Patent Number 5,545,192. Issue Date: 8/13/96; Country: U.S.
Method of Facilitating the Physiological Adaption to an Activity/Rest Schedule and	Czeisler CA , Kronauer RE, Allan JS. Assignee: Brigham and Women's Hospital. Patent Number 363440. Issue Date: 5/14/97; Country: Europe (Recorded in Austria, Belgium, France, Germany, Italy, Luxembourg, Netherlands, Sweden, Switzerland, Liechtenstein & Great Britain).

Apparatus for
Prescribing a
Substantially
Optimum Stimulus
Regimen of Pulses of
Bright Light to
Allow a Subject's
Circadian Cycle to be
Modified to a
Desired State.

Method and Device
for Modifying the
Circadian Cycle in
Humans.

Czeisler CA, Kronauer RE, Allan JS. Assignee: Brigham and Women's Hospital. Patent Number 477282. Issue Date: 5/14/97; Country: Europe (Recorded in Austria, Belgium, Switzerland, Liechtenstein, Germany, Denmark, Spain, France, Great Britain, Italy, Luxembourg, Netherlands & Sweden).

Assessment and
Modification of a
Subject's

Czeisler CA, Kronauer RE, Allan JS. Assignee: Brigham and Women's Hospital. Patent Number 2739725. Issue Date: 1/24/98; Country: Japan.

Endogenous
Circadian Cycle.

Modification of
Endogenous
Circadian
Pacemaker.

Czeisler CA, Kronauer RE, Allan JS. Assignee: Brigham and Women's Hospital. Patent Number 2928636. Issue Date: 5/14/99; Country: Japan.

Test for evaluation of
visual functioning in
visually impaired
subjects

Czeisler CA, Martens H, Shanahan TL. Assignee: Brigham and Women's Hospital. Filing Date: 6/15/92; Country: WO.

Method for
modifying or
resetting the
circadian cycle using
short wavelength
light

Brainard GC, **Czeisler CA**, Kronauer RE, Lockley SW. Brigham and Women's Hospital. Filing Date: 7/14/04; Country: WO. CA. JP. U.S (util)
Brainard GC, **Czeisler CA**, Kronauer RE, Lockley SW. Brigham and Women's Hospital. Filing Date: 4/25/05; Country: U.S. (pct)

High sensitivity of
the human circadian
pacemaker to
resetting by short
wavelength light.

Brainard GC, **Czeisler CA**, Kronauer RE, Lockley SW. Brigham and Women's Hospital. Filing Date: 7/14/04; Country: EP

Report of Education of Patients and Service to the Community

Activities

- | | |
|------|---|
| 2008 | Panelist, Discovery Panel, NASA Future Forums. Museum of Science, Boston, MA
http://www.nasa.gov/50th/future_forums/bostonWithGallery.html |
| 2011 | Invited Speaker "Sleep to Thrive" TEDx Cambridge 'Thrive', Cambridge, MA
http://www.tedxcambridge.com/thrive/charles-a-czeisler/ |
| 2012 | Invited Speaker webcast FORUM presentation, Harvard School of Public Health, Boston, MA |

“FIGHTING THE CLOCK: How America’s Sleep Deficit is Damaging Long-term Health”

<http://theforum.sph.harvard.edu/events/sleep-deprivation-fighting-the-clock>

2012

Invited Speaker, “The City Dark” AAAS Washington, DC

http://www.aaas.org/news/releases/2012/0531night_sky.shtml

Report of Scholarship

Peer reviewed publications in print or other media

Research Investigations

1. **Czeisler CA**, Moore-Ede MC, Regestein QR, Kisch ES, Fang VS, Ehrlich EN. Episodic 24-hour cortisol secretory patterns in patients awaiting elective cardiac surgery. *J Clin Endocrinol Metab* 1976; 42:273-283. PMID: 1262431
2. Kokkoris CP, Weitzman ED, Pollak CP, Spielman AJ, **Czeisler CA**, Bradlow H. Long term ambulatory temperature monitoring in a subject with a hypnnychthemeral sleep-wake cycle disturbance. *Sleep* 1978; 1:177-190. PMID: 756061
3. **Czeisler CA**, Weitzman ED, Moor e-Ede MC, Zimmerman JC, Knauer RS. Human sleep: its duration and organization depend on its circadian phase. *Science* 1980; 210:1264-1267. PMID: 7434029
4. Lydic R, Schoene WC, **Czeisler CA**, Moore-Ede MC. Suprachiasmatic region of the human hypothalamus: homolog to the primate circadian pacemaker? *Sleep* 1980; 2:355-362. PMID: 6773133
5. **Czeisler CA**, Zimmerman JC, Ronda J, Moore-Ede MC, Weitzman ED. Timing of REM sleep is coupled to the circadian rhythm of body temperature in man. *Sleep* 1980; 2:329-346. PMID: 7403736
6. Weitzman ED, **Czeisler CA**, Zimmerman JC, Ronda JM. Timing of REM and stages 3 + 4 sleep during temporal isolation in man. *Sleep* 1980; 2:391-408. PMID: 7403740
7. Zimmerman JC, **Czeisler CA**, Laxminarayan S, Knauer RS, Weitzman ED. REM density is dissociated from REM sleep timing during free-running sleep episodes. *Sleep* 1980; 2:409-416. PMID: 7403741
8. **Czeisler CA**, Richardson GS, Coleman RM, Zimmerman JC, Moore-Ede MC, Dement WC, Weitzman Ed. Chronotherapy: resetting the circadian clocks of patients with delayed sleep phase insomnia. *Sleep* 1981; 4:1-21. PMID: 7232967
9. Weitzman ED, **Czeisler CA**, Coleman RM, Spielman AJ, Zimmerman JC, Dement WC, Richardson GS, Pollak CP. Delayed sleep phase syndrome: a chronobiological disorder with sleep-onset insomnia. *Archiv Gen Psychiatry* 1981; 38:737-746. PMID: 7247637
10. **Czeisler CA**, Richardson GS, Zimmerman JC, Moore-Ede MC, Weitzman ED. Entrainment of human circadian rhythms by light-dark cycles: a reassessment. *Photochem Photobiol* 1981; 34:239-247. PMID: 7267730
11. Bernstein IL, Zimmerman JC, **Czeisler CA**, Weitzman ED. Meal patterns in free-running humans. *Physiol Behav* 1981; 27:621-623. PMID: 7323164
12. Kronauer RE, **Czeisler CA**, Pilato SF, Moore-Ede MC, Weitzman ED. Mathematical model of the human circadian system with two interacting oscillators. *Am J Physiol* 1982; 242:R3-R17. PMID: 7058927
13. Weitzman ED, Moline ML, **Czeisler CA**, Zimmerman JC. Chronobiology of aging: temperature, sleep-

wake rhythms and entrainment. *Neurobiol Aging* 1982; 3: 299-309. PMID: 7170047

14. **Czeisler CA**, Moore-Ede MC, Coleman RM. Rotating shift work schedules that disrupt sleep are improved by applying circadian principles. *Science* 1982; 217:460-463. PMID: 7089576
15. Weitzman ED, Zimmerman JC, **Czeisler CA**, Ronda J. Cortisol secretion is inhibited during sleep in normal man. *J Clin Endocrinol Metab* 1983; 56:352-358. PMID: 6822642
16. Gander PH, Kronauer RE, **Czeisler CA**, Moore-Ede MC. Simulating the action of zeitgebers on a coupled two-oscillator model of the human circadian system. *Am J Physiol* 1984;247:R418-R426. PMID: 6476142
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19. Muller JE, Stone PH, Turi ZG, Rutherford JD, **Czeisler CA**, Parker C, Poole WK, Hartwell TD, Scheiner E, Gold HK, Jaffe AS, Raabe DS, Rude RE, Passamani E, Roberts R, Robertson T, Sobel BE, Willerson JT, Braunwald E, and the MILIS study group. Circadian variation in the frequency of onset of acute myocardial infarction. *N Engl J Med* 1985; 313:1315-1322. PMID: 2865677
20. Strogatz SH, Kronauer RE, **Czeisler CA**. Circadian regulation dominates homeostatic control of sleep length and prior wake length in humans. *Sleep* 1986; 9:353-364. PMID: 3505735
21. Moline ML, Monk TH, Wagner DR, Pollak CP, Kream J, Fookson JE, Weitzman ED, **Czeisler CA**. Human growth hormone release is decreased during sleep in temporal isolation (free-running). *Chronobiologia* 1986; 13:13-19. PMID: 3720426
22. Gordon NP, Cleary PD, Parker CE, **Czeisler CA**. The prevalence and health impact of shift work. *Am J Pub Health* 1986; 76:1225-1228. PMID: 3752325; PMCID: PMC1646676.
23. **Czeisler CA**, Allan JS, Strogatz SH, Ronda JM, Sánchez R, Ríos CD, Freitag WO, Richardson GS, Kronauer RE. Bright light resets the human circadian pacemaker independent of the timing of the sleep-wake cycle. *Science* 1986; 233:667-671. PMID: 3726555
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posture. *Circulation* 1988; 78: 35-40. PMID: 3289790

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30. Shanahan TL, **Czeisler CA**. Light exposure induces equivalent phase shifts of the endogenous circadian rhythms of circulating plasma melatonin and core body temperature in men. *J Clin Endocrinol Metab* 1991; 73:227-235. PMID: 1856258
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38. Allan JS and **Czeisler CA**. Persistence of the circadian thyrotropin rhythm under constant conditions and after light-induced shifts of circadian phase. *J Clin Endocrinol Metab* 1994; 79:508-512. PMID: 8045970
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shift work environment. *J Occup Med* 1994; 36:1295-1300. PMID: 7884570

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46. Boivin DB, Duffy JF, Kronauer RE, **Czeisler CA**. Dose-response relationships for resetting of human circadian clock by light. *Nature* 1996; 379:540-542. PMID: 8596632
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66. **Czeisler CA**, Duffy JF, Shanahan TL, Brown EN, Mitchell JF, Rimmer DW, Ronda JM, Silva EJ, Allan JS, Emens JS, Dijk DJ, Kronauer RE. Stability, precision, and near-24-hour period of the human

circadian pacemaker. *Science* 1999; 284: 2177-2181. PMID: 10381883

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76. Khalsa SBS, Jewett ME, Duffy JF, **Czeisler CA**. The timing of the human circadian clock is accurately represented by the core body temperature rhythm following phase shifts to a three-cycle light stimulus near the critical zone. *J Biol Rhythms* 2000; 15:524-530. PMID: 11106069
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Professional educational materials or reports, in print or other media

Television Documentaries

The Infinite Voyage: Chronobiology (WQED, PBS/Pittsburgh)—Served on five-member expert advisory panel for this documentary in a series co-produced by WQED and the NAS under the auspices of the National Academy of Sciences Film Committee. 1989. Michael S. Shaw, MD, Lee Bobker, Dita Domonkos (Producers and Directors).

Journey Into Sleep (Health Science Media). 1990 Winner: Cine Golden Eagle Film & Video Competition. William Bensen (Senior Producer/Director), Darrell Mohr (Producer/Editor), Jennifer Pulley (Host).

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Narrative Report

Charles A. Czeisler, Ph.D., M.D. is the Baldino Professor of Sleep Medicine, Director of the Division of Sleep Medicine at Harvard Medical School and Chief of the Division of Sleep Medicine in the Department of Medicine at Brigham and Women's Hospital in Boston, Massachusetts. Dr. Czeisler has more than 30 years' experience in the field of basic and applied research on the physiology of the human circadian timing system and its relationship to the sleep-wake cycle including the application of sleep science and sleep medicine to occupational medicine/health policy. He is interested in the physiology of the hypothalamic circadian pacemaker in humans, photic and non-photic synchronizers of the human circadian pacemaker, temporal

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Research Fellow, International Institute of Management, Berlin, Germany, 1976

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Publications

Books and Monographs:

Drug Regulation and Innovation: Empirical Evidence and Policy Options, (American Enterprise Institute for Public Policy Research: Washington, D.C.), 1976.

The Impact of Regulation on Industrial Innovation (with John Vernon) (National Academy of Sciences: Washington, D.C.), 1979.

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“Innovative Structure and Performance of the Pharmaceutical Industry,” Second International Conference on the Economics of Innovation, University of Milan, Piacenza, Italy, June 1992.

“Pharmaceuticals and Health Care Costs,” International Health Care Forum on Health Care Policy and the Pharmaceutical Industry, Gotemba, Japan, October 1992.

“Innovation and Structural Change in Pharmaceuticals and Biotechnology,” American Economic Association Meetings, Anaheim, California, January 1993.

“Pharmaceutical R&D Costs, Prices and Profits,” Conference on Pharmaceutical Industry Research, Innovation and Public Policy, Harvard University, John F. Kennedy School of Government, February 1993.

“Pharmaceutical R&D Returns: Prospects Under Health Care Reform,” American Enterprise Institute Conference on Competitive Strategies in the Pharmaceutical Industry, October 1993.

“Health Care Reform--Implications for Pharmaceutical Innovation,” Drug Information Association Workshop on Health Economics, Lisbon, Portugal, November 1993.

“The Administration's Health Reform Plan--Implications for Pharmaceutical Innovation,” testimony before Congressman Waxman's House Subcommittee on Health and the Environment, February 1994.

“Socially Optimal Reimbursement and Utilization Policies for Pharmaceuticals,” Hungarian National Social Insurance Administration, Budapest, Hungary, April 1994.

“Pharmaceuticals and Quality of Life: An Economist's Perspective,” Forum Engelberg, Engelberg, Switzerland, April 1994.

“Price and Profit Control, New Competitive Dynamics and the Economics of Innovation in the Pharmaceutical Industry,” Office of Health Economics Symposium on Industrial Policy, London, England, June 1994.

“Health Reform and Pharmaceutical Innovation,” American Enterprise Institute, Washington, D.C., July 1994.

“R&D Costs, Innovational Output and Firm Size,” Yale University Festschrift Honoring Merton J. Peck, New Haven, Connecticut, September 1994.

“The Effects of Increased Government Purchases on Vaccine R&D,” testimony before the Subcommittee on Health and the Environment on the Vaccines for Children's Program, June 1995.

“PharmacoEconomics and Pharmaceutical Innovation,” to IFPMA Conference on PharmacoEconomics in the year 2000, Geneva, Switzerland, February 1995.

“Development of New Pharmaceuticals,” to the Third Princeton Conference on Drug Discovery and Development, Princeton, New Jersey, May 1995.

“Longer Patents for Increased Generic Competition: The Waxman-Hatch Act After One Decade,” Tufts University Conference on Cost Containment Health Care Reform and Pharmaceutical Innovation, Talloires, France, July 1995.

“The Roles of Government in the Drug Regulation Process: Lessons from Other Nations,” presented to Conference on Health Financing and Health Economics, Beijing, China, October 1995.

“The Use of Cost-Effectiveness Analysis by Pharmaceutical Benefit Management Companies,” to Duke University Conference on Cost-Effectiveness Analysis in Decision Making, November 1995.

“The Effects of the Waxman Hatch Act on Drug Innovation and Generic Competition,” Testimony before the U.S. Senate Judiciary Committee, March 1996.

“International Patent Policies and Pharmaceutical Innovation,” to University of Vienna, May 1996.

“Public Policies and Pharmaceutical Innovation” to Jagellion University, Krakow, Poland, May 1996.

“Financing Health Care in Pharmaceuticals and Biotechnology,” to OECD Workshop, Paris, July 1996.

“Health Care and Innovation” to Seminar on Approaches to Cost Containment in Health Care, Kasteel de Willenburg, The Hague, October 1996.

“Pharmaceutical Innovation, Cost-Effectiveness Research and Emerging Regulatory Issues,” American Enterprise Institute, Washington, D.C., November 1996.

“The Role of Cost-Effectiveness Analysis in Managed Care,” Tufts University Center for the Study of Drug Development Conference, Talloires, France, July 1997.

“Public Policy and Innovation in Pharmaceuticals and Biotechnology,” Business and Economics Society International Conference, Athens, Greece, July 1997.

“The Determinants of Pharmaceutical Research and Development Expenditures,” Schumpeterian Society Meetings, Vienna, Austria, June 1998.

“Effective Patent Life in Pharmaceuticals,” U.S. House of Representatives Colloquium for House Staff Members, June 1999.

“The Distribution of Sales from Pharmaceutical Innovation,” Schumpeterian Society Meetings, Manchester England, June, 2000.

“New Research on the Returns to Pharmaceutical R&D,” American Enterprise Institute, Washington, D.C., October 2000.

“Patent Policy Issues in Pharmaceuticals” Robert Wood Johnson Foundation Colloquium on the Pharmaceutical Industry, Washington, D.C., March 2001.

“Returns to Pharmaceutical R&D in the 1990s” Tufts University Conference, Center for the Study of Drug Development, Talloires, France, July, 2001.

“Patents, Innovation and Access to New Pharmaceuticals,” American Association for the Advancement of Science, Annual Meetings, Boston, February 2002.

“Patents and the Development of New Pharmaceuticals in Pharmaceuticals and Biotechnology Industry,” Federal Reserve Bank of Dallas, April 2002.

“Returns to Pharmaceutical R&D,” American Economic Association Meetings, Washington, DC, January 2003.

“Increasing R&D Incentives for Neglected Diseases,” Duke University Law School Conference, April 2003; St. Vincent’s College, September 2003; Georgetown University, October 2003, Columbia University, December 2003.

“Are the Economics of Pharmaceutical R&D Changing? Productivity, Patents, and Political Pressures,” Tufts University Center for the Study of Drug Development Conference, Talloires, France, July 2003.

“Global Returns on R&D From New Drug Introductions,” Keio University, Tokyo, Japan, September 2003.

“R&D Costs and Returns by Therapeutic Category,” Southern Economic Association Meetings, San Antonio, Texas, November 2003.

“The Hatch-Waxman Act and Drug Innovation,” Food and Drug Law Institute Conference, Washington, DC, December 2004.

“Developing Drugs for Developing Countries,” American Economic Association Meetings, Philadelphia, PA, January 2005; also International Health Economics Congress, Barcelona, Spain, July 2005.

“The Development of New Vaccines,” University of Chicago Conference on Vaccines, May 2005.

“Generic Competition in Pharmaceuticals,” International Conference on Pharmaceutical Innovation, Taipei, Taiwan, May 2005.

“Impact of Generic Competition on Pharmaceutical Markets,” International Health Economics Congress, Barcelona, Spain, July 2005.

“Worldwide Trends In New Drug Introductions: Economic and Policy Issues,” Second European Meeting on Pharmaceutical Policy, Madrid, Spain, April 2006.

“Legacy of Hatch Waxman Act: Patents Generics and Litigation,” Cornerstone Research Conference, Nevis, West Indies, May 2006.

“Entry and Competition in Follow-On Biologics.” Congressional Budget Office, Washington, DC. March 2007.

“R&D Costs for New Biopharmaceuticals,” BIO International Meetings, Boston, MA, May 2007.

“Data Exclusivity for Follow-On Biologics,” American Enterprise Institute, Washington, DC, June 2007.

“Economic Issues for Follow-on Biologics,” National Academy of Sciences, Washington, DC, November 2008.

“Priority Review Vouchers for Neglected Diseases,” Office of Health Economics, London, England, June 2009.

“Mergers and Alliances in Pharmaceuticals,” University of Pennsylvania Wharton School, November 2009.

“Implementation of an Abbreviated Pathway for Biosimilars,” American Economic Association Meetings, Atlanta, Georgia, January 2010.

“Economic and Policy Issues in Implementing a Biosimilar Pathway,” Seton Hall Law School, Newark, New Jersey, October 2010.

“Paragraph IV Challenge Outcomes,” International Health Economics Association Meeting, July 2011.

“The Market for U.S. Biosimilars: Prospects and Lessons from Abroad.” American Society of Health Economists Meeting, Cornell University, June 2012.

“FDA Regulation of Biosimilars,” Harvard Law School Conference on The FDA in the 21st Century, May 2013.

“Biosimilar Competition: Lessons from Europe and Prospects for the U.S.” Office of Health Economics, London, May 2013.

Research Grants and Government Projects:

Principal Investigator, National Science Foundation Grant to Yale University, “Collaborative Research on Determinants of Selected Firm Outlays,” June 1969 - December 1970. (\$9,800.00)

Principal Investigator, National Science Foundation Grant to NBER for research on “The Returns to Firm Investment Outlays, Plant and Equipment and Advertising Outlays,” 1972-1974. (\$47,900.00)

Principal Investigator, National Science Foundation Grant for Research on “The Effect of Product Quality Regulation on Innovation: The Case of the U.S. Ethical Pharmaceutical Industry,” 1975-1978. (\$111,700.00)

Consultant, Federal Trade Commission project on “The Effects of Repealing Anti-Substitution Laws on Drug Innovation,” 1977-1978.

Study Rapporteur, National Academy of Sciences Committee on Technology and International Economic and Trade Issues, “The Impact of Government Regulation on Innovation,” 1978-1979.

Principal Investigator, National Science Foundation Grant to Duke University for “Studies on Drug Substitution, Patent Policy and Innovation,” 1979-1982. (\$125,979.00)

Advisory Panel Member, Office of Technology Assessment, The Patent System and Its Assessment on New Technological Enterprises, 1982-1983.

Principal Investigator, Environmental Protection Agency Grant to Investigate the Effects of Regulation on Innovation in Pesticides, (with Kip Viscusi of the Fuqua School of Business), 1983-1984.

Member, Committee on Public-Private Sector Relations in Vaccine Innovation,” Institute of Medicine, National Academy of Sciences, 1983-1985.

Principal Investigator, General Accounting Office, Research Project on the Effects of Different State Regulations on Automobile Insurance Premiums and Availability, 1984-1985.

Principal Investigator, Duke University, Program in Pharmaceuticals and Health Economics, Project on Cost Containment and Pharmaceutical Innovation, 1985-1991.

Principal Investigator, Duke University, Program in Pharmaceuticals and Health Economics, Project on Returns to Pharmaceutical R&D, 1990-1994.

Principal Investigator, Program in Pharmaceuticals and Health Economics, “Public Policy and Innovation in the Vaccine Industry,” 1995-1997.

Principal Investigator, Program in Pharmaceuticals and Health Economics, “New Research on the Costs and Returns to R&D” 1998-2002.

Principal Investigator, “Increasing R&D Incentives for Neglected Diseases” (with David Ridley and Jeff Moe) 2003–2006.

Principal Investigator, “Advancing Chemoprevention Agents Through the Definition of Legal Barriers and Solutions in Patent, Intellectual Property, Liability, and Tax Laws.” C-Change grant, Washington, DC, 2007 (with Jeff Moe of Fuqua School of Business).

Tab E

CURRICULUM VITAE

Date Prepared: January 24, 2022

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Place of Birth Stoke-on-Trent, UK

ORCID: <https://orcid.org/0000-0001-5209-2881>

Education

1992	B.Sc.(Hons)	Biology	University of Manchester, UK
1997	Ph.D.	Biological Sciences (J Arendt PhD, DJ Skene PhD)	University of Surrey, UK

Postdoctoral Training

1997	Research Officer	Biological Sciences (J Arendt PhD)	University of Surrey
1997-2000	Research Fellow	Biological Sciences (J Arendt PhD)	University of Surrey

2000-2002	Research Fellow	Medicine (CA Czeisler PhD MD)	Brigham and Women's Hospital, Boston, MA
2000-2002	Research Fellow	Medicine (CA Czeisler PhD MD)	Harvard Medical School, Boston, MA

Faculty Academic Appointments

1994-1996	Honorary Research Officer	Ophthalmology	Moorfields Eye Hospital, London, UK
1999-2000	Lecturer (0.5 FTE)	Biochemistry	University of Surrey
2003	Instructor	Medicine	Harvard Medical School
2003-2004	Lecturer	Biochemistry	University of Surrey
2003-2005	Lecturer (Academic, part-time)	Medicine	Harvard Medical School
2005	Instructor	Medicine	Harvard Medical School
2005-2011	Assistant Professor	Medicine	Harvard Medical School
2007-2010	Honorary Associate Professor	Sleep Medicine	Clinical Sciences Research Institute, Warwick Medical School, UK
2008-2009	Honorary Associate Professor	Psychology, Psychiatry and Psychological Medicine	Monash University, Australia
2009	Adjunct Associate Professor	Psychology, Psychiatry and Psychological Medicine	Monash University, Australia
2010-2013	Adjunct Associate Professor	Psychology and Psychiatry	Monash University, Australia
2010-2013	Research Associate	Sleep and Chronobiology	Woolcock Institute of Medical Research, Australia
2011-2013	Associate Professor	Medicine	Harvard Medical School

2013	Adjunct Professor	Psychological Sciences	Monash University, Australia
2014-present	Associate Professor (Academic, part-time)	Medicine	Harvard Medical School
2014	Adjunct Professor (0.4 FTE)	Psychological Sciences	Monash University, Australia
2015-2019	Adjunct Professor (0.4 FTE)	Neuroscience	Monash Institute of Cognitive and Clinical Neurosciences, Monash University, Australia
2015-present	Affiliated Faculty	Public Health	Center for Health and the Global Environment, Harvard School of Public Health
2020-present	Adjunct Professor, Vice-Chancellor's Fellow (0.2 FTE)	Sleep and Chronobiology	Surrey Sleep Research Centre, School of Biosciences and Medicine, Faculty of Health and Medical Sciences, University of Surrey, UK

Appointments at Hospitals/Affiliated Institutions

2003-2011	Associate Neuroscientist	Medicine	Brigham and Women's Hospital
2011-2013	Neuroscientist	Medicine	Brigham and Women's Hospital
2014-present	Neuroscientist, part-time (0.5-0.8 FTE)	Medicine and Neurology	Brigham and Women's Hospital

Other Professional Positions

2003	Expert Witness	Paul V. Mulkern, Jr., Milton, MA
2004	Consultant on federally-funded research	Brigham and Women's Hospital, Boston
2007	Consultant on federally-funded research	Warwick Medical School, U.K.
2007	Expert Witness	Proskauer Rose LLC, New York, NY
2008	Consultant	Apollo Lighting, American Fork, UT
2008-2013	Consultant on federally-funded research	Thomas Jefferson University, PA
2009	Consultant	American Family
2009-2010	Consultant	Wyle Integrated Science and Engineering

		/ NASA, Houston, TX
2010-2015, 2016-present	Consultant	KBR Wyle Services / NASA, Houston (formally Wyle Science, Technology and Engineering Group)
2010-2018	Consultant	Headwaters Inc, Marblehead, MA
2010-2013	Consultant	NatureBright Company, Irvine, CA
2011	Expert Witness	Armstrong Management Lawyers, Calgary, Alberta, Canada
2011	Expert Report	Rothstein Law Firm, PA
2011-2012	Expert Witness	Hicks Morley Hamilton Stewart Storie LLP, Toronto, Ontario, Canada
2012	Expert Witness	Cox & Palmer, Fredericton, New Brunswick, Canada
2013-2016 unless noted	Consultant (short meetings [30-60 minutes] reviewing public clinical data with financial firms)	2013 unless noted; Blackrock, Cowen and Company, Endurant Capital Management, Far West Capital Management, Fidelity, Frankel Group, Impax Labs, Kearney Venture Partners, Lazard Capital Markets, New Horizon Capital, Noble Insights (2018), Perceptive Advisors (2014), Polar Capital, ResearchWorks Inc, Serrado Capital (2015), Slingshot Insights (2016), Wyvern Funds
2013-2019	Consultant and Chair, Scientific Advisory Board	PlanLED, WA
2013-present	Member, Scientific Advisory Board (unpaid)	Midwest Lighting Institute, Madison, WI (non-profit)
2013-present	Co-owner	iSleep PTY, Australia (not active)
2013, 2014	Expert Witness	Hicks Morley Hamilton Stewart Storie LLP, Toronto, Ontario, Canada
2013-2015	Theme Leader ‘Smart Lighting’	CRC for Alertness, Safety and Productivity, Monash University, Australia (non-profit)
2014	Expert Report	Dunsmore Law Professional Corporation, Toronto, Ontario, Canada
2014-2017	Consultant	Pegasus Capital Advisors LP, NY
2014-2015, 2016-2017	Consultant and Member, Scientific Advisory Board, WELL Living Labs	Delos, NY

2014	Consultant on government-funded research	Carbon Limiting Technologies Ltd, UK on behalf of PhotonStar LED Group PLC, UK
2014-2021	Consultant and Member, Scientific Advisory Board (2014)	Hints Performance AG, Switzerland
2015-2016	Expert Report	Phillips Lytle LLP, Buffalo, NY
2015-2016	Consultant	OpTerra Energy Services Inc, CA
2015-2019	Program Leader 'Safety and Productivity Improvements'	CRC for Alertness, Safety and Productivity, Monash University, Australia (non-profit)
2015-2020	Consultant	Akili Interactive, MA
2016	Consultant	Atlanta Hawks, AT
2016	Consultant	Atlanta Falcons, AT
2016-present	Consultant	Light Cognitive, Helsinki, Finland
2017	Consultant	Team C Racing, CA
2017-2018	Consultant	Noble Insights, NY
2017-2018	Consultant	BHP Billiton, Australia
2017-2020	Consultant	Mental Workout, NY
2017	Consultant and Member, Scientific Advisory Board	Consumer Sleep Solutions, CA
2017-2021	Consultant and Member, Scientific Advisory Board (2020-2021)	Lighting Science Group Corporation / HealthE, Warwick, RI
2017-2019	Consultant	Six Senses, Bangkok, Thailand
2018-2021	Expert Report / Witness	McCullough, Hill, Leary PS, WA
2018-2020	Consultant	Stantec, MA
2018-present	Consultant	Apex 2100 Ltd, UK
2018-present	Expert Report / Witness	Paul, Weiss, Rifkind, Wharton & Garrison LLP, NY
2019	Consultant	Eyejust, NY
2020-present	Consultant	View Inc., CA
2021-present	Consultant	Timeshifter Inc., NY
2021-present	Consultant	Sleep Standards, FL

Major Administrative Leadership Positions**Local**

2001	Co-Director, Kleitman Summer Fellowship Program in Human Circadian Biology	Division of Sleep Medicine, Brigham and Women's Hospital
2003-2007	Co-Director (with Prof JW Hastings), Chautauqua NSF Short Courses for College Teachers 'Circadian Biology'	Harvard University
2005-2006	Director, Summer Internship Program in Reproductive and Hormonal Risk Factors for Breast Cancer in Blind Women	Division of Sleep Medicine, Brigham and Women's Hospital
2006-present	Director, Circadian Physiology Program, Division of Sleep and Circadian Disorders	Department of Medicine, Brigham and Women's Hospital
2008	Co-Director (with Prof JW Hastings), Harvard Summer School course 'Circadian Biology'	Harvard University

National

2009	Organizing Committee, American Society for Photobiology Topical Symposium	Thomas Jefferson University, Philadelphia
2012-present	Advisory Board	School Start Later
2012-present	Medical Advisory Board	Circadian Sleep Disorders Network
2012-2017	Member	Human Centric Lighting Design Committee
2014-2015	Member	Advisory Council, U.S. Green Building Council and the Harvard Center for Health and the Global Environment

International

2005	Co-Director (with Prof R.G. Foster and Prof D-J. Dijk) Fatigue, Sleep and Biological Clocks International Conference (Linbury Trust)	Imperial College, London, UK
2010-2011	Scientific Organizing Committee, Working Time Society meeting	Stockholm, Sweden

2014	Member, Program Committee	Experiencing Light 2014, Eindhoven, The Netherlands
2016	Co-Director (with Prof D.J. Skene) The therapeutic use of melatonin and melatonin agonists: Past discoveries, present practice and future directions (Vanda Pharmaceuticals Inc.)	Royal Society of Medicine, London, UK

Committee Service

Local

2006-2016	Member, Chronobiology Core Management Advisory Committee	Division of Sleep Medicine, Brigham and Women's Hospital
2006-present	Member, Curriculum Development Sub-Committee	Training Program in Sleep, Circadian and Respiratory Neurobiology, Division of Sleep Medicine, Harvard Medical School
2007-2010	Member, Tracking and Evaluation Sub-Committee	Training Program in Sleep, Circadian and Respiratory Neurobiology, Division of Sleep Medicine, Harvard Medical School
2007-2018	Member, Fellows Selection Committee	Division of Sleep Medicine, Brigham and Women's Hospital
2013-2016	Member, Harvard Catalyst Clinical Research Center Scientific Review Committee	Center for Clinical Investigation, Brigham and Women's Hospital
2015-2020	Member, Administrative Core Management Advisory Committee	Division of Sleep and Circadian Disorders, Brigham and Women's Hospital

National

2008-present	Subject Matter Expert (SME) 'Recommendation regarding the solid state lighting module LED light as a replacement for current ISS General Luminaire Assemblies (GLAs)'	Human Research Program, NASA Johnson Space Center
2009-present	Member, Sleep Risk Mitigation Analysis Tool (RMAT) Panel	Human Research Program, NASA Johnson Space Center
2013-2014	Consultant, ACGIH Threshold Limit Values (TLVs) for Physical Agents Committee	American Conference of Governmental Industrial Hygienists
2018-present	Member, DOE SSL Light-Physiology Interest Group	Facilitated by Department of Energy

2020	Science Team Member, TIM Circuits and Biomarkers of the Central Nervous System Relating to Astronaut Performance	Human Research Program, NASA Johnson Space Center
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International

2005-2009 2009-present	Member, Light and Health Committee Vice-Chair, Light and Health Committee	Illuminating Engineering Society (IES) of North America
2005	Member, Short-Term Working Group on Medical Nocturnal Shiftwork	Royal College of Physicians, UK
2009-present	Member, Spaceflight Human Behavior and Performance Working Group (SHBPWG) Subgroup on Circadian Desynchrony, International Space Station Multilateral Medical Operations Panel (MMOP)	Human Research Program, NASA Johnson Space Center
2011-2013	Expert Advisor, Circadian Rhythm Workgroup, International Classification of Sleep Disorders Revision Task Force	American Academy of Sleep Medicine (AASM)
2015	Member, Royal College of Physicians Working Group on Fatigue	Royal College of Physicians, UK

Professional Societies

1996-2000	European Pineal and Biological Rhythms Society	Member
1997-2000	British Sleep Society	Member
2002-2004, 2019, 2021	Society for Research on Biological Rhythms	Member
2003-2004	European Sleep Research Society	Member
2004-present	Sleep Research Society	Member
	2004-present	Member
	2006-2007	Member, Communications Committee
	2007-2010	Chair, Communications Committee
2005-present	International Dark-Sky Association	Member
2007-present	Working Time Society	Member
2009	New York Academy of Sciences	Member
2009	American Society for Photobiology	Member
2012	Society for Neuroscience	Member
2012-2013	Endocrine Society	Member

Grant Review Activities

2004	Exploratory Research Award Program Review Committee, Uniformed Services University of the Health Sciences, Bethesda, MD	Ad hoc Member
2007	Grant Review Committee Thresher Research Fund	Ad hoc Member
2007	Grant Review Committee Sleep Research Society	Ad hoc Member
2007	Grant Review Committee, Health Services and Public Health Research Board, Medical Research Council, UK	Ad hoc Member
2020	Grant Review Harvard Catalyst Translational Innovator Sight & Science Funding Opportunity	Ad hoc Reviewer

Editorial Activities**Ad Hoc Reviewer**

American Journal of Physiology - Regulatory, Integrative and Comparative Physiology (2002, 2007)

Archives of General Psychiatry (1998)

Behavioral Brain Functions (2013)

Behavioral Neuroscience (2004)

Bioelectromagnetics (2005)

Biological Psychiatry (1998, 2005)

Bipolar Disorders (2005)

BMC Psychiatry (2014)

Brain Research Reviews (2004)

British Journal of Sports Medicine (2000)

Cancer Causes and Control (2012)

Chronobiology International (2007, 2008, 2019)

Clocks and Sleep (2018)

Cochrane Reviews (2016)

Current Biology (2006)

Current Eye Research (2008)

Environmental Health Perspectives (2008)

European Journal of Applied Physiology (2009)

European Journal of Neuroscience (2004)
 European Journal of Physiology (1998)
 Journal of the American Medical Association (2003)
 Journal of Biological Rhythms (2000-2005, 2008, 2010, 2011, 2013)
 Journal of Clinical Endocrinology and Metabolism (1999)
 Journal of Clinical Investigation (2015)
 Journal of Clinical Sleep Medicine (2011)
 Journal of Neurology (2000)
 Journal of Physiology (2011)
 Journal of Pineal Research (2019, 2020, 2021)
 Journal of the Royal Society of Health (2009)
 Journal of Sleep Research (1998, 2008, 2009)
 Lighting Research and Technology (2011)
 Medical Letter (2014)
 Nature and Science of Sleep (2020)
 Neuroscience Letters (1998)
 PLoS One (2007, 2013)
 Proceedings of the National Academy of Sciences USA (2017)
 Sleep (1998, 1999, 2002-2009, 2020)
 Sleep and Biological Rhythms (2012)
 Sleep Medicine (2007, 2016)
 Sleep Medicine Reviews (1998, 2005)

Other Editorial Roles

2006-present	Editorial Board (Journal)	<i>Sleep</i>
2007-present	Editorial Advisory Board	Sleep and Health Education Program, Division of Sleep Medicine, Harvard Medical School
2008-2013	Editorial Board (Journal)	<i>Open Sleep Journal</i>
2010, 2018	Book Co-Editor	<i>Sleep, Health and Society: From Aetiology to Public Health</i> (two editions)
2010-2020	Associate Editorial Board (Journal)	<i>Frontiers in Neurology - Sleep Disorders</i>
2011	Book Section Editor, <i>Circadian Rhythms Section</i>	<i>Therapy in Sleep Medicine</i> , Amsterdam, The Netherlands: Elsevier; 2011.

2012-2013	Expert Review Panel	<i>Non-24-hour circadian rhythm disorder</i> , National Sleep Foundation
2018-present	Editorial Board (Journal)	<i>Clocks and Sleep</i>
2019-present	Associate Editor (1 of 5) (Journal)	<i>Journal of Pineal Research</i> (IF: 15.2)

Honors and Prizes

2000-2004	International Prize Research Travelling Fellowship	Wellcome Trust, UK	Research
2000	Conference Grant	Royal Society, UK	Research
2000	Overseas Conference Grant	University of Surrey, UK	Research
2002	Representative Research Fellow, Division of Sleep Medicine, BWH	Research Council Research Fellows Exhibition	Research
2004	Young Investigator Award	Sleep Research Society	Research
2005	Executive Director Special Award	International Dark-Sky Association	Research
2006	Healthy Sleep Community Award (as part of the Harvard Work Hours Health and Safety Group)	National Sleep Foundation	Research
2006	Participant in HMS Leadership Development Conference	Harvard Medical School	Leadership
2009	Harvard-Australia Fellowship	Harvard Club of Australia Foundation	Research
2009	Taylor Technical Talent Award	Illuminating Engineering Society of North America (IES)	Research
2010	Distinguished Service Award	Sleep Research Society	Administration
2011	Group Achievement Award (as part of the Chilean Miners NASA Rescue Support Team)	NASA	Sleep medicine advice
2014	Johnston Space Center Center Director's Innovation Team Award	NASA	Lighting countermeasure development and advice

(as part of the ISS Flexible
Lighting Team)

2015	Excellence in Research Award	Human Centric Lighting Society	Lighting applications
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Report of Funded and Unfunded Projects

Funding Information

Past

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| 1993-1996 | <p>Role of melatonin and other 5-methoxyindoles in human photic information processing (PI: J Arendt PhD)
South Thames Regional Health Authority, UK
Ph.D. student
Major Goals: To understand the relationship between visual impairment and circadian rhythms disorders in the real world, particularly melatonin, sleep and alertness rhythms.</p> |
| 1994-1996 | <p>Circadian rhythm disorders in the blind (PI: J Arendt PhD)
Institut de Recherches Internationales Servier, France
Ph.D. student
Major Goals: To understand the relationship between visual impairment and circadian rhythms disorders in the real world, particularly melatonin, sleep and alertness rhythms.</p> |
| 1997-2000 | <p>Circadian function and its regulation in blind subjects (PI: DJ Skene PhD)
Wellcome Trust, UK 048197/Z/96/Z
Postdoctoral Fellow
Major Goals: To develop and test appropriately timed melatonin administration to treat non-24-hour sleep-wake disorder in totally blind individuals.</p> |
| 2000 | <p>Quantitative EEG monitoring and vigilance: Effect of sleep deprivation, circadian phase and sympathetic activation (PI: DJ Dijk PhD)
National Space Biomedical Research Institute
Co-Investigator
Major Goals: To understand the interaction between homeostatic and circadian control of sleep, performance and sympathetic activation.</p> |
| 2000-2002 | <p>Determination of the endogenous tau of the human circadian system in the absence of light and the influence if non-photic time cues
Wellcome Trust, UK 060018/Z/99/Z
PI (£ 87,312)
Major Goals: To define the endogenous period of the human circadian system and to examine the influence of non-photic time cues on circadian rhythmicity.</p> |
| 2001-2004 | <p>Effects of extended work hours on ICU patient safety (PI: CA Czeisler PhD, MD)
Agency for Healthcare Research and Quality R01HS12032
Co-Investigator
Major Goals: To study the effects of abolishing extended duration 24-h on-call shifts and reducing weekly work hours on medical interns' medical error rates.</p> |

- 2001-2005 After effects of entrainment on human circadian period (PI: CA Czeisler PhD, MD)
National Institute of Neurologic Disorders and Stroke R01NS40982
Co-Investigator
Major Goals: To investigate the role of after-effects of entrainment to photic and nonphotic time cues on intrinsic circadian period in the blind.
- 2001-2005 Effects of extended work hours on intern health and safety (PI: CA Czeisler PhD, MD)
National Institutes of Occupational Safety and Health R01OH07567
Co-Investigator
Major Goals: To study the effects of abolishing extended duration 24-h on-call shifts and reducing weekly work hours on medical interns' sleep, fatigue and performance.
- 2001-2006 Ocular control of melatonin regulation: Action Spectrum (PI: GC Brainard PhD)
National Institute of Neurologic Disorders and Stroke R01NS36590
Co-Investigator
Major Goals: To assess whether circadian phase-resetting by light is wavelength dependent and to test whether the spectral sensitivity differs from photopic and scotopic photoreception used for vision.
- 2003-2004 Effects of caffeine administration on circadian entrainment, sleep, alertness and performance in free-running blind people
Wellcome Trust (UK) 060018/C/99/Z
PI (£ 55,416)
Major Goals: To test whether daily caffeine administration can reentrain free-running circadian rhythms in totally blind people living under real-world conditions.
- 2004-2005 A new method for treating sleep disorders (PI: ES Nuwayser PhD)
Small Business Innovative Research program R44NS043129
Co-Investigator
Major Goals: To test the safety and effectiveness of a transdermal delivery system for melatonin and its effects on sleep during the day in a simulated shiftwork paradigm.
- 2004-2008 Reproductive and hormonal risk factors for breast cancer in blind women
Department of Defense Breast Cancer Research Program Idea Award W81XWH-04-1-0553
PI (\$305,994)
Major Goals: To test the hypotheses that 1) that breast cancer incidence is lower in visually impaired compared to sighted women; 2) that visually impaired women with no photic input to the pineal gland will have higher levels of melatonin than those with 24-h rhythms; 3) that breast cancer in the visually impaired is associated with low levels of melatonin, high levels of estradiol, and/or other markers of reproductive history.
- 2004-2008 Optimizing light spectrum for long duration space flight (PI: GC Brainard PhD)
National Space Biomedical Research Institute HPF00403
Co-Investigator
Major Goals: To determine the best wavelengths of light for resetting circadian phase and alerting the brain to develop light as a countermeasure for long duration space flight.
- 2004-2008 Circadian entrainment, sleep-wake regulation and neurobehavioral performance during extended duration spaceflight (PI: CA Czeisler PhD, MD)

- National Space Biomedical Research Institute HPF00402
Consultant
Major Goals: To study the effect of blue-enriched light as a countermeasure to circadian desynchrony caused by simulated shiftwork schedules used during spaceflight.
- 2004-2008 Sleep disorders management, health and safety in police (PI: CA Czeisler PhD, MD)
Centers for Disease Control and Prevention R01OH008496
Co-Investigator
Major Goals: To conduct a randomized, prospective study of a sleep disorders detection and treatment program on performance, health and safety in police officers.
- 2004-2009 Testing the effectiveness of a comprehensive fatigue management for the police (PI: CA Czeisler PhD, MD)
National Institutes of Justice 2004FSBX0001
Co-Investigator
Major Goals: To conduct a randomized, prospective study of a home-based sleep apnea detection and treatment program on performance, health and safety in police officers.
- 2004-2010 Mechanism underlying the effects of blue light in humans
National Center for Complementary and Alternative Medicine R01AT002129
PI (\$ 1,086,356)
Major goals: To investigate the effects of different colors of light on human physiology and test the claims that specific colors of light preferentially stimulate neurobiological, physiological and endocrinological systems.
- 2005-2009 Effects of light at night on the circadian system in nurses (PI: ES Schernhammer MD PhD)
National Institutes of Occupational Safety and Health R01OH008171
Co-Investigator
Major Goals: To assess melatonin and light exposure of shift-working nurses using a novel ambulatory technology designed to measure short wavelength light.
- 2005-2009 Implementing reduced work hours for all ICU staff to improve patient safety (PI: CP Landrigan MD)
Agency for Healthcare Research and Quality U18HS015906
Co-Investigator
Major Goals: To conduct a before-after study of the effects on sleep and patient safety of unit-wide implementation of an ACGME-compliant resident work schedule.
- 2005-2010 Photoc and nonphotoc input to the human circadian system
National Institute of Neurologic Disorders and Stroke R01NS040982
PI (\$ 928,846)
Major goals: To study 1) the effects of 460nm and 555nm light in non-visual responses to light in visually blind subjects and 2) the entraining effects of living on a 'day' length 0.4 h advanced relative to intrinsic period blind subjects insensitive to light.
- 2006-2007 Testing the effectiveness of a comprehensive police fatigue management program
'Operation Healthy Sleep'
ResMed Foundation Scientific Research Grant (Research Project)
PI (\$ 85,366)

- Major Goals: To conduct a study on the utility of a home-based sleep apnea detection system for identifying police officers at high risk for obstructive sleep apnea.
- 2006-2007 UK Residents' Work Hours Research Programme (PI: FC Cappuccio MD)
National Health Service (NHS) Workforce Commissioned Research Programme, UK
Co-Investigator
Major Goals: To conduct a pilot study to assess the safety implications of the change from 56-h to 48-h week rotas for junior doctors on patient safety and physicians' sleep.
- 2006-2012 Treatment of circadian sleep disorders with bright light (PI: SW Lockley PhD)
National Institute of Mental Health R01MH045130
PI (\$ 1,072,290)
Major Goals: In this study we would systematically assess the circadian phase-shifting, melatonin suppressing, and alertness-enhancing response to a monochromatic light stimulus, using a wavelength (460 nm) that has been shown to maximally stimulate the circadian system
- 2007-2008 Assessment of AHI by ApneaLink under laboratory and home-based conditions in police officers with and without obstructive sleep apnea
ResMed Foundation Scientific Research Grant (Research Project)
PI (\$ 48,338)
Major Goals: To conduct a study to validate a home-based sleep apnea detection system against laboratory-based polysomnographical recordings for identifying apneas.
- 2007-2008 Short wavelength countermeasure for circadian desynchrony (PI: D Adams)
Air Force Office of Scientific Research STTR Phase I FA9550-07-C-0058
Subcontract PI (\$ 47,619)
Major Goals: To develop a scientifically-grounded approach to adjust human circadian phase through photic stimulation of the melanopsin photoreceptor system.
- 2007-2010 Evaluation of the potential for translation to practice of a sleep disorders management program for police (PI: CA Czeisler PhD, MD)
Centers for Disease Control and Prevention R01OH009403
Co-Investigator
Major Goals: We propose to evaluate the potential for translation and external validity of the Operation Healthy Sleep program in police officers.
- 2007-2010 Phoenix Scout Lander: Countermeasures test-bed for spaceflight ground controllers (PI: LK Barger PhD)
National Aeronautics and Space Administration NNX08AD66A
Co-Investigator
Major Goals: To determine the feasibility and acceptability of laboratory-tested fatigue countermeasures for improving sleep, alertness, performance and circadian for ground controller who will be working on the 24.6 hour Mars sol during the Phoenix mission.
- 2007-2010 The effectiveness of exposure to different colours of light in improving alertness during the day after sleep loss (PI: SW Rajaratnam PhD)
National Health and Medical Research Council, Australia, Project Grant 436758
Chief (Co-) Investigator C
Major Goals: To establish the spectral sensitivity for the effects of different colors of

- visible light on a range of light-induced alerting responses in humans during the day.
- 2007-2011 Characteristics of light exposure necessary for development of optimal countermeasures to facilitate circadian adaptation and enhance alertness and cognitive performance in space
National Space Biomedical Research Institute HPF01301
PI (\$ 1,000,000)
Major Goals: We aim to test the effect of light intensity (high, low) and timing (night, day) on the spectral sensitivity of the circadian, neuroendocrine and neurobehavioral effects of light.
- 2007-2012 Blue light for enhancing alertness in space missions (PI: GC Brainard PhD)
National Aeronautics and Space Administration HPF00001
Consultant
Major Goals: To determine the best wavelengths of light for stimulating the acute alerting effects of light on sleepiness and performance.
- 2007-2014 Desensitization of circadian responses to light (PI: CA Czeisler PhD, MD)
National Institute of Neurological Disorders and Stroke R01NS054277
Co-Investigator
Major Goals: To quantify the role of prior light exposure, particularly prior light exposure duration, on melatonin suppression and the alerting effects of light at night.
- 2008-2009 A spectrally dynamic berth light for active circadian cycle management (PI: L Li PhD)
DARPA SBIR Phase I W31P4Q-09-C-0171
Subcontract PI (\$ 19,841)
Major Goals: To develop and test novel LED technologies for resetting circadian rhythms and improving alertness in submariners.
- 2008-2010 Acute alerting effects of exposure to blue light (GoLITE) during the day
Apollo Health Inc. / Philips (Investigator-initiated trial)
PI (\$ 60,800)
Major Goals: To test the hypotheses that three hours of blue LED light exposure during the day will be more effective at improving alertness and performance than exposure to an equal photon density of green LED light using the same device.
- 2008-2010 Acute alerting effects of exposure to high color temperature fluorescent light during the day
Philips (Investigator-initiated trial)
PI (\$ 175,904)
Major Goals: To test the hypotheses that three hours of high CCT (17000K) fluorescent light exposure during the day will be more effective at improving alertness and performance than exposure to an equal photon density of low CCT (4100K) light.
- 2008-2010 Effect of AcrySof® Natural blue light filtration on circadian rhythms
Alcon Laboratories Inc. (Investigator-initiated trial)
PI (\$ 27,486)
Major Goals: To test the hypothesis that patients fitted with AcrySof Natural IOLs will have a significantly improved sleep and circadian melatonin phase after cataract surgery.
- 2008-2011 A comprehensive firefighter fatigue management program 'Operation Healthy Sleep'

- Department of Homeland Security FEMA EMW-2007-FP-02197 (PI: CA Czeisler PhD, MD)
Co-Investigator
Major Goals: To conduct a randomized, prospective study of a sleep disorders detection and treatment program on performance, health and safety in firefighters.
- 2008-2012 Optimizing light for long duration space exploration (PI: GC Brainard PhD)
National Space Biomedical Research Institute HPF01605
Co-Investigator
Major Goals: To determine the best wavelengths of light for resetting circadian phase and alerting the brain to develop light as a countermeasure for long duration space flight.
- 2009 2009 Australia-Harvard Fellowship
Harvard Club of Australia Foundation
PI (AU\$15,000)
Major Goals: To consolidate and expand ongoing collaborative research, educational and training initiatives with Monash University and the Australasian Sleep Trials Network.
- 2009-2010 Operational evaluation of a photic countermeasure to improve alertness, performance, and mood during nightshift work on a 105-day study (105-day Russian Chamber Study) (PI: CA Czeisler PhD, MD)
National Space Biomedical Research Institute HFP00002
Co-Investigator
Major Goals: To validate the efficacy and operational feasibility of a lighting countermeasure to improve alertness and performance during night-shift work occurring during long-duration space missions.
- 2009-2010 An investigation of drowsiness while driving in hospital night shift workers and sleep disorder patients: The Monash Drowsy Driving (MONRI) Study (PI: SW Rajaratnam PhD)
Monash University Strategic Grant, Monash University, Australia
Co-Investigator
Major Goals: This pilot study aims to assess the base rate of drowsy driving in hospital nurses working night shifts and sleep apnea patients using a real-world fatigue measure.
- 2009-2010 Réponses cérébrales à la lumière chez des personnes non-voyantes (PI: J Carrier, PhD)
Fonds de Recherche en Santé du Québec (FRSQ), Canada
Co-Investigator
Major Goals: To test fMRI brain activation in response to short wavelength blue light exposure in totally visually blind subjects with intact circadian photoreception.
- 2009-2011 Developing a risk index of healthcare provider alertness to improve safety (PI: CP Landrigan MD)
Agency for Healthcare Research and Quality (AHRQ) R03HS017357
Co-Investigator
Major Goals: To extend our current mathematical model of circadian rhythms, sleep and performance and alertness so that it can be used to develop a risk index of healthcare provider alertness.
- 2009-2011 Human circadian sensitivity of very short light pulses (PI: EB Klerman, MD, PhD)

- National Heart Lung and Blood Institute 1RC2HL101340
Co-Investigator
Major Goals: To test the circadian phase resetting effects of very short (several minute) pulses of white light.
- 2009-2012 Effects of the circadian clock and light on the production of estrogens
National Institute of Environmental Health Sciences R21ES017112
PI (\$ 125,000)
Major Goals: To test the relationship between the circadian 24-hour rhythms in melatonin and estrogen and the role of light on estrogen endocrinology.
- 2009-2012 National Firefighter Sleep Disorders Management Program: Translation to Practice. (PI: CA Czeisler PhD, MD)
Department of Homeland Security FEMA EMW-2008-FP-02566
Co-Investigator
Major Goals: To compare and contract three different methods for implementing and disseminating a sleep disorders detection and treatment program on performance, health and safety in firefighters.
- 2009-2012 Feasibility pilot study on acute biological and behavioral responses to the solid state lighting module for the International Space Station (PI: G.C. Brainard)
National Aeronautics and Space Administration NNX09AM68G
Subcontract PI (\$ 19,736)
Major Goals: To test the acute alerting effects of a novel solid-state lighting module being developed for installation in the International Space Station.
- 2009-2013 Validation of assessment tests and countermeasures for detecting and mitigating changes in cognitive function during robotics operations (PI: CM Oman PhD)
National Space Biomedical Research Institute NBPF02001
Subcontract PI (\$ 666,667)
Major Goals: To test the efficacy of the fatigue countermeasures short wavelength light and/or caffeine to improve cognition during simulated robotic operations.
- 2009-2013 Randomised controlled trial of a light intervention to enhance alertness and performance in night shiftworkers (PI: SW Rajaratnam PhD)
National Health and Medical Research Council, Australia, Project Grant 545871
Chief (Co-) Investigator D
Major Goals: In a randomized, controlled trial, we will test the efficacy of a novel therapeutic light intervention to improve alertness and neurobehavioral function due to sleep loss and circadian rhythm disruption in night shiftworkers.
- 2009-2014 Assessment of circadian phase for the diagnosis and treatment of sleep phase insomnia
Philips Respironics (Investigator-initiated trial)
PI (\$ 360,487)
Major Goals: To establish the prevalence of sleep phase insomnia within the general insomnia population and define the clinical ‘norms’ for sleep and circadian phase timing.
- 2010 Clinical Research Support Agreement (PI: S.W. Lockley, PhD)
Vanda Pharmaceuticals
PI (\$76,660)

- Major Goals: Assist in the development of clinical trials to test the efficacy of a melatonin agonist to treat non-24-hour rhythms in totally blind patients.
- 2010-2011 Melatonin and prostate cancer: A biomarker study among men in the Reykjavik cohort (PI: LA Mucci)
Harvard Clinical and Translational Science Center Pilot Grant.
Co-Investigator
Major Goals: To study melatonin levels, genetic determinants and pineal gland structure in relation to prostate cancer risk and progression in a study nested in the prospective AGES Reykjavik Cohort.
- 2010-2012 The role of sleep and circadian phase on crew safety, performance and psychological health during long-term analog space missions
National Aeronautics and Space Administration 08-MMAMA08-0035
PI (\$ 127,024)
Major Goals: To evaluate crew health, safety and psychology in personnel wintering-over in Antarctica as a high fidelity analog of mission operations during long-duration Lunar and Mars missions.
- 2010-2012 Improving the efficacy of light therapy: A comparative study to determine whether exposure to intermittent light enhances circadian, neuroendocrine, and alerting responses relative to exposure to continuous light (PI: JJ Gooley, PhD)
National Medical Research Council Singapore, New Investigator Grant
Co-Investigator
Major Goals: To test the role of intermittent versus continuous monochromatic light on circadian, neuroendocrine and neurobehavioral responses.
- 2010-2012 ‘The impact of a resident work schedule change on patient safety’ (PI: N. Ayas)
Partnerships for Health System Improvement (PHSI) Program Grant, Canada
Co-investigator
Major goals: To assess the impact of eliminating shifts >24 hours on both patient safety and education of medical residents in two hospitals in British Columbia.
- 2010-2013 Harvard University exercise tolerance as a predictor of firefighters’ future risks (PI: S.N. Kales SN)
Department of Homeland Security FEMA
Consultant
Major Goals: To examine whether decreased exercise tolerance will be associated with increased risks for adverse health and safety outcomes for firefighters in both prospective and retrospective analyses.
- 2010-2014 Identification of cardiometabolic vulnerabilities caused by effects of synergistic stressors that are commonly encountered during space missions (PI: S.A. Shea)
National Aeronautics and Space Administration NNX10AR10G
Co-Investigator
Major Goals: To assess the effects of simulated shift patterns as experienced during long-duration space flight, on metabolic and cardiovascular markers of health.
- 2011-2012 Assessment of ocular measures of alertness and driving impairment in medical residents (PI: M.E. Howard)

Institute for Breathing and Sleep (IBAS) Research Grant

Co-Investigator

Major Goals: This project will assess on road driving performance and episodes of drowsiness whilst driving in medical residents following extended duty night shifts.

- 2011-2013 A multicenter, randomized, double-mask, placebo-controlled, parallel study to investigate the efficacy and safety of 20 mg Tasimelteon versus placebo on totally blind subjects with N24HSWD followed by an OLE phase
Vanda Pharmaceuticals (Sponsor-initiated trial)
Site PI (\$347,502)
- 2011-2013 Efficacy of light therapy for sleepiness and fatigue following TBI (PI: J. Ponsford)
Victorian Neurotrauma Initiative
Co-Investigator
Major Goals: To study the effect of short-wavelength light as a potential fatigue countermeasure in patients with traumatic brain injury.
- 2011-2014 Clinical trial of an intervention to reduce fatigue and improve safety and health in Firefighters (PI: CA Czeisler PhD, MD)
Department of Homeland Security FEMA EMW-2010-FP-00521
Co-Investigator
Major Goals: To conduct a station-level, randomized clinical trial of policies designed to maximize sleep opportunities during current 24-hour shifts to improve alertness, performance, health and safety in firefighters.
- 2012-2013 A randomized withdrawal study to demonstrate the maintenance of effect of 20 mg tasimelteon in the treatment of N24HSWD
Vanda Pharmaceuticals (Sponsor-initiated trial)
Site PI (\$74,974)
- 2012-2013 Screening for obstructive sleep apnea in National Football League Players (PI: C.A. Czeisler PhD, MD)
National Football League Charities
Co-Investigator
Major Goals: This project will establish an NFL-wide system of identifying those at high risk of OSA and further evaluating those at high risk.
- 2012-2014 Open-label safety study of a 24-month 20 mg dose regimen of tasimelteon for the treatment of non-24-hour sleep-wake disorder (N24HSWD) in blind individuals with no light perception
Vanda Pharmaceuticals (Sponsor-initiated trial)
Site PI
- 2012-2014 Randomised Controlled Trial Of Melatonin For Delayed Sleep Phase Disorder' (PI: SW Rajaratnam PhD)
National Health and Medical Research Council, Australia, Project Grant 1031513
Chief (Co-) Investigator D
Major Goals: The primary aim is to test in a randomized, double-blind, parallel groups, placebo-controlled, outpatient trial, the efficacy and safety of melatonin (0.5mg) for treatment of Delayed Sleep Phase Disorder (DSPD).

- 2012-2015 Investigating the effects of evening light exposure on melatonin suppression, alertness and nocturnal sleep.
Biological Illumination LLC (Investigator-initiated trial)
PI (\$ 485,556)
Major Goals: To compare the effects of a novel blue-depleted light source on melatonin suppression and sleep with a standard compact fluorescent source.
- 2013 The role of sleep and circadian phase on crew safety, performance and psychological health during long-term analog space missions (Co-PIs: T. L. Sletten PhD and S.M.W. Rajaratnam, PhD)
NHMRC Centre for Integrated Research and Understanding of Sleep (CIRUS)
Co-Investigator
Major Goals: To evaluate crew health, safety and psychology in personnel wintering-over in Antarctica as a high fidelity analog of mission operations during long-duration Lunar and Mars missions.
- 2013-2014 Evaluation of Rio Tinto Iron Ore (WA)'s mental health systems.
Rio Tinto Iron Ore (Service Agreement)
PI (\$ 428,937)
Major Goals: To conduct a review of RTIO's mental health strategy and identify major gaps with current best practice.
- 2013-2014 Development of an algorithm for predicting which individuals are highly vulnerable versus highly resilient to the effects of sleep loss on performance (PI: C.A. Czeisler, PhD, MD)
Defense Advanced Research Projects Agency DARPA-BAA-11-65
Co-investigator
Major Goals: To identify, develop and test candidate predictive biomarkers of sleepiness and impaired performance for future testing and validation in large, prospective cohort studies.
- 2013-2014 Clinical Research Support Agreement (PI: S.W. Lockley, PhD)
Vanda Pharmaceuticals
PI (\$144,920)
Major Goals: Assist in the dissemination and publication of data from clinical trials to test the efficacy of a melatonin agonist to treat non-24-hour rhythms in totally blind patients.
- 2014 LED lighting in schools (PI: S.M.W. Rajaratnam, PhD)
Department of Education and Communities, New South Wales, Australia (Consulting)
Co-Investigator
- 2014-2017 Circadian mechanisms for sex differences in shift work tolerance (PI: SW Cain PhD)
National Health and Medical Research Council, Australia, Project Grant 1064231
Chief (Co-) Investigator D
Major Goals: This study is designed to examine sex differences in the effect of office-level light on the biological clock during a simulated night shift.
- 2015-2017 Hyper-sensitivity of the circadian system to light in Delayed Sleep Phase Disorder (PI: SW Cain PhD)

- National Health and Medical Research Council, Australia, Project Grant 1087665
Chief (Co-) Investigator E
- 2015-2017 Investigation of blue-enriched light as a countermeasure for automobile driver sleepiness and fatigue (PI: C.M. Oman PhD)
Co-Investigator (Subcontract \$177,839 Direct, \$225,855 Total)
Ford-MIT Alliance Request for Ideas
- 2009-2015 ‘A comprehensive fatigue management program and an evaluation of a photic countermeasure for mission controllers’. (CO-PI: CA Czeisler PhD, MD, LK Barger PhD)
National Aeronautics and Space Administration NNX10AF47G
Co-Investigator
Major goals: To develop and test a multifaceted fatigue management program in NASA ground crew including education, sleep disorders screening and treatment and light therapy to improve circadian adaptation and alertness.
- 2009-2015 Efficacy of melatonin treatment in a phase advance model of insomnia (PI: JF Duffy PhD)
National Institute of Neurologic Disorders and Stroke R01HL093279
Co-Investigator
Major Goals: To test the chronobiotic and sleep promoting effects of melatonin in a phase advance model of insomnia.
- 2012-2015 The ISS Dynamic Lighting Schedule: An in-flight lighting countermeasure to facilitate circadian adaptation, improve sleep and enhance alertness and performance on the International Space Station.
National Space Biomedical Research Institute HFP02801
PI (\$900,000)
Major Goals: To study how new lighting would be used operationally to provide a countermeasure to shiftwork in a high-fidelity simulation of the ISS lighting environment, sleep patterns, and work schedule.
- 2012-2019 Multi-center trial of work-hour limits for PGY 2&3 resident work hours on patient safety (Co-PIs: CA Czeisler PhD, MD and CP Landrigan MD)
National Heart, Lung and Blood Institute U01HL111478
Co-Investigator
Major Goals: To conduct a randomized study in six ICUs nationwide to test whether a scientifically-founded intervention schedule will result in a decrease in preventable injuries to patients and resident physicians’ motor vehicle crashes, and increase resident sleep and vigilance.
- 2013-2015 Investigating the role of photic and non-photoc cues on entraining human peripheral metabolic rhythms.
Vanda Pharmaceuticals (Investigator-initiated trial)
PI (\$ 48,335)
Major Goals: To test the hypothesis that human peripheral metabolic rhythms are synchronized by non-photoc meal-schedules and not the central circadian pacemaker.
- 2013-2018 Impact of eliminating extended duration work shifts on intern health and safety (PI: LK

- Barger PhD)
National Institute of Occupational Safety and Health R01
Co-Investigator
- 2014-2019 Cooperative Research Centre (CRC) for Alertness, Safety and Productivity
Investigator (~\$25,000,000)
- 2014-2020 Development and testing of biomarkers to determine individual astronauts' vulnerabilities to behavioral health disruptions (PI: SW Lockley PhD; Co-PI: CA Czeisler, PhD, MD)
PI (\$944,883 Direct, \$1,200,000 Total)
National Aeronautics and Space Administration NNX14AK53G
Major Goals: To examine traditional and novel biomarkers of impairment due to sleep loss or circadian disruption under laboratory and operational conditions.
- 2015-2017 Ultra-short light pulses as an efficient countermeasure for circadian misalignment and objective performance and subjective alertness decrements
National Space Biomedical Research Institute HFP02801
Co-Investigator
Major Goals: To study how new lighting would be used operationally to provide a countermeasure to shiftwork in a high-fidelity simulation of the ISS lighting environment, sleep patterns, and work schedule.
- 2015-2020 Lighting Protocols for Exploration – HERA Campaign (PI: SW Lockley PhD)
PI (\$125,000)
National Aeronautics and Space Administration NNX15AM28G
Major Goals: To examine the feasibility and efficacy of a Dynamic Lighting System to improve alertness, sleep and circadian rhythms in the Human Exploration Research Analog and to finalize the operational procedures for in-flight testing of new lighting aboard the ISS.
- 2016-2017 Technologies to target circadian rhythm disruption in PTSD (PI: A Dowling, PhD)
STTR A16A-T014 Technologies to Target Circadian Rhythm Disruption in PTSD
Co-Investigator (Site PI)
- 2016-2018 Clinical relevance of circadian and sleep timing in cancer patients: a systems medicine approach
Monash Warwick Alliance
Co-Investigator
Major Goals: This project aims at better understanding the interactions between sleep, the Circadian Timing System (CTS) and anticancer drug response, in order to design personalised and dynamic behavioural interventions and/or chronotherapeutic strategies.
- 2016-2020 Circadian lipidomics in constant routine, forced desynchrony, and non-lab setting (PI: B Kristal PhD)
National Heart, Lung and Blood Institute R01HL132556
Co-Investigator
Major Goals: We propose to utilize the analytical and bioinformatics platforms and experience in population-level metabolomics studies to study banked plasma samples from well-characterized individuals in tightly controlled circadian rhythm studies to

- determine circadian phase from a single blood sample based on the lipidomic profiles.
- 2016-2020 Measuring the effects of light from electronic devices on sleep (PI: SW Lockley PhD)
PI (\$12,500)
F.Lux Software LLC (Investigator-initiated trial)
Major goals: To assess the effects of software to reduce blue light screen emissions on sleep.
- 2018-2019 Senior care facility lighting to improve health, safety and energy efficiency (PI: SA Rahman PhD)
Civil Money Penalty (CMP) Funds, State of Wisconsin via subcontract from Midwest Lighting Institute
Co-Investigator
Major Goals: To conduct a pilot study in two WI nursing home facilities to implement lighting protocols that will help residents' health and safety.
- 2019-2020 In-home light therapy to reduce fatigue, sleepiness and sleep disturbance following TBI and stroke (PI: J Ponsford, PhD)
MICCN Strategic Grant, Monash University, Australia
Co-Investigator (CI-2)
Major Goals: This pilot study aims to assess the impact of dynamic lighting on clinical fatigue outcomes in TBI and stroke patients.
- 2019-2020 Comparison across multiple types of sleep deprivation (PIs: EB Klerman, MD, PhD; CA Czeisler, PhD, MD)
Federal Aviation Authority
Co-Investigator
Major Goals: This contracted work will collect data for the FAA for discovery of biomarkers associated with neurobehavioral or cognitive impairment during sleep loss and mistimed sleep.
- 2019-2021 Effect of light on health and safety in an inpatient behavioral health unit (PI: SA Rahman, PhD)
Co-investigator
Battelle Memorial Institute (Pacific Northwest Division) through the Department of Energy (Investigator-initiated trial)
Major goals: The goals are to assess the role of light on health outcomes in an inpatient facility.
- 2020-2021 Fatigue and shift mitigation project: The SAFER trial
PI (£75,000)
National Police Wellbeing Service and the Police and Crime Commissioner for Lancashire, UK, Project Grant
Major Goals: We have developed a programme to identify and quantify issues related to Sleep, Alertness and Fatigue in Emergency Responders: the SAFER Programme for UK police. We will survey police officers and establish the risk of sleep disorders, fatigue and burnout.

Current

- 2014-2022 Testing solid state lighting countermeasures to improve circadian adaptation, sleep, and performance during high fidelity analog and flight studies for the International Space Station (PI: GC Brainard PhD; Co-PI: SW Lockley PhD)
Co-PI (Subcontract \$726,173)
National Aeronautics and Space Administration NNX15AC14G
Major Goals: To assess the impact of dynamic lighting protocols on circadian rhythms, sleep and performance during spaceflight.
- 2019-2022 Towards a real-time estimate of circadian phase during spaceflight (PI: MA St Hilaire PhD)
National Aeronautics and Space Administration 80NSSC20K0576
Co-Investigator
Major Goals: To develop a feasible method to measure circadian phase accurately and reliably in real-time during spaceflight.
- 2019-2022 Urine metabolomics to estimate internal clock time (PI: MA St Hilaire PhD)
National Institute of Nursing Research R21 NR018974
Co-Investigator
Major Goals: To develop a feasible method to measure circadian phase accurately and reliably using non-invasive urinomics.
- 2019-2022 Assessment of circadian and light interactions in adolescent sleepiness (PI: S.M.W. Rajaratnam, PhD)
Australian Research Council (ARC) Discovery Project (DP190103444)
Co-Investigator (Partner Investigator)
Major Goals: This study will use state-of-the-art measures of the biological clock, rigorous assessment of light exposure and sophisticated analytical approaches to comprehensively and prospectively examine the relative contributions of multiple biological clock and sleep factors that may be linked to cognitive function and sleepiness in adolescents.
- 2019-2024 Clinical Research Support Agreement (PI: S.W. Lockley, PhD)
Vanda Pharmaceuticals
PI (\$TBD)
Major Goals: Assist in data review and publication of data from clinical trials to test the efficacy of a melatonin agonist to treat circadian and other disorders.
- 2020-2025 Effects of daytime lighting conditions on students' cognitive performance (PI: SA Rahman, PhD)
Co-investigator
Seoul Semiconductor (Investigator-initiated trial)
Major goals: The goal is to assess the role light spectrum and intensity on the alerting effects of daytime light exposure.

- 2020-2025 The effect of lighting supplementation on cognitive task performance during the day (PI: SA Rahman, PhD)
Co-investigator
BIOS, LLC (Investigator-initiated trial)
Major goals: The goal of this project is to examine whether supplementing existing poor quality indoor lighting with blue-enriched white lighting can improve daytime cognitive performance in healthy young adults.
- 2021 University of Surrey tender for Fatigue Risk Assessment Tool: Phase 1 (PI: AC Skeldon, PhD)
Co-investigator
Transport for London, UK, Project Grant
Major Goals: To evaluate fatigue management tools for London bus drivers.
- 2021-2022 The SAFER Programme: Improving sleep and fatigue in UK police officers and staff PI (£70,000)
National Police Wellbeing Service, UK, Project Grant
Major Goals: To implement a national programme to identify and quantify issues related to Sleep, Alertness and Fatigue in Emergency Responders: the SAFER Programme for UK police. We will survey police officers and establish the risk of sleep disorders, fatigue and burnout.
- 2021-2023 Validation of real-time field-based markers of circadian phase (PI: M.A. St. Hilaire, PhD)
National Institutes of Health R03AG071922
Co-Investigator
Major Goals: The major goals of this project are to use commercially available point-of-care devices to measure internal clock time in real-time at home from biomarkers that exhibit robust circadian rhythms
- 2021-2025 A multicenter, double-blind, randomized study to evaluate the effects of tasimelteon vs. placebo in participants with Delayed Sleep-Wake Phase Disorder (DSWPD)
Vanda Pharmaceuticals (Sponsor-initiated trial)
Site PI
- 2021-2025 Determining the role of photic and non-photoc time cues in resetting lipid circadian rhythms in humans (PI: S.A. Rahman, PhD, MPH)
National Institutes of Health NHLBI R01HL159207
Co-Investigator
Major Goals: The goal of this project is to construct three PRCs that systematically examine the contribution of light and meal timing on resetting lipid circadian rhythms.

Report of Local Teaching and Training

Teaching of Students in Courses

Harvard University

2001	MCB289 Photobiology 8 undergraduate and graduate students	Molecular and Cellular Biology 1 x 1 h lecture
2001-2002	MCB186 Circadian Biology 9-12 undergraduate and graduate students	Molecular and Cellular Biology Teaching Fellow; 12 x 2 h sections
2001-2002 2005-2014	MCB186 Circadian Biology 9-20 undergraduate and graduate students	Molecular and Cellular Biology 1-2 x 1 h lectures
2011-2014	MCB186 Circadian Biology 9-20 undergraduate and graduate students	Molecular and Cellular Biology Course Faculty; attend 12 x 3 h classes
2019	GEN ED1038; Sleep 250 undergraduate students	Program in General Education Teaching Fellow; 12 x 1.25 h sections
2020	GEN ED1038; Sleep 300 undergraduate students	Program in General Education Invited guest panelist; 2 x 1.25 h classes

Graduate School of Design, Harvard University

2008-2009 2011	Day-Lighting Buildings (GSD 6332) ~10 undergraduate and graduate students	Harvard Graduate School of Design 1 x ~1.5 h lecture
2010-2013	Day-Lighting Buildings Executive Education Summer Program ~20 professional architects	Harvard Graduate School of Design 1 x 1.5 h lecture
2019-2021	Building Human Interaction (SCI-6361) ~20 undergraduate and graduate students	Harvard Graduate School of Design 1 x 1.5 h lecture

Harvard School of Public Health

2011-2020	EH 232 Occupational and Environmental Medicine ~20-60 medical residents	Harvard School of Public Health 1 x 1-1.5 h lecture
2016, 2019	ENVR E-119c High Performance Buildings for Health, Comfort, and Sustainability ~60 in-person and online students	Harvard School of Public Health 1 x 1.5 h lecture
2016	EH 252 The Impact of Buildings on Health, Productivity and Sustainability ~8 students	Harvard School of Public Health 1 x 2 h lecture

Massachusetts Institute of Technology, Cambridge

2009, 2012, 2015, 2019	Daylighting (4.430) ~10 undergraduate and graduate students	Department of Architecture 1 x 1.5 h lecture
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Brigham and Women's Hospital

2001	Kleitman Summer Fellowship Program in Human Circadian Biology 23 undergraduate and graduate students	Division of Sleep Medicine 1 x 1 h lecture
2001	Research Seminar 15 research assistants	General Clinical Research Center (GCRC) 1 x 1 h lecture
2001	Graduate Medical Education Group 10-member committee	Department of Medicine 1 x 1 h lecture
2006	Core Laboratory Research Seminar 10 research assistants and faculty	General Clinical Research Center (GCRC) 1 x 1 h lecture
2012	Research Seminar 15 research assistants	General Clinical Research Center (GCRC) 1 x 1 h lecture

University of Surrey, UK

1996	M.Sc. in Clinical Biochemistry 25 postgraduate Masters (M.Sc.) students	School of Biological Sciences 8 h/week x 4 weeks of practical classes
1999	EIHMS 1.20: Body Systems 130 1 st -year undergraduate nursing students	Eur Inst of Health & Medical Sciences 4 h lectures, 1 h tutorial
2000, 2004	SBS346: Biological Rhythms 8-10 Final year undergraduate students	School of Biological Sciences 2 (2000) or 1 x 1 h lectures
2000	SBS111: Physiology 110 1 st -year undergraduate students	School of Biological Sciences 30 h of practical classes, 20 h marking

Warwick Medical School, UK

2004	Special Study Module: Sleep Medicine	Warwick Medical School
2007-2010	10 medical students	2 x 3 h lectures (2004), 1 x 2 h lecture

Monash University, Australia

2009	BNS3052 Drugs, Brain and Altered Awareness 30 undergraduate students	School of Psychology and Psychiatry and Psychological Medicine 1 x 2 h lecture, 1 x 2 h laboratory class
2016	PSY3320 Sleep and Circadian Rhythms ~200 undergraduate students	School of Psychological Sciences 1 x 2 h lecture

Formal Teaching of Residents, Clinical Fellows and Research Fellows (post-docs)

2007-2009,	Preceptors' Introductory Sleep Course,	Division of Sleep Medicine, Harvard
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2012, 2016	Training Program in Sleep, Circadian and Respiratory Neurobiology ~15 Pre- and post-doctoral trainees	Medical School 1 x 1.5 h lecture
2008, 2011-2013, 2016, 2018-2021	Sleep Medicine Clinical Fellowship Program ~6-12 Clinical Fellows	Beth-Israel Deaconess Medical Center 1 x 1-1.5 h lecture
2008, 2010, 2019-2021	Sleep Medicine Clinical Fellowship Program ~6-12 Clinical Fellows	Brigham and Women's Hospital 1 x 1-2 h lecture
2009	Neuroscience Graduate Program ~40 Clinical Fellows and Faculty	Thomas Jefferson University 1 x 1 h lecture
2012-2015	Harvard Longwood Psychiatry Residency Program ~15 PGY2-3 Residents	Brigham and Women's Hospital 1 x 1 h didactic session
2021	Morehouse School of Medicine Graduate Program ~5 Post-doctoral trainees	Morehouse School of Medicine 1 x 1 h lecture

Clinical Supervisory and Training Responsibilities

2006-2010	Associate Preceptor	NHLBI T32 Training Program in Sleep, Circadian and Respiratory Neurobiology, Division of Sleep Medicine, Harvard Medical School
2010-present	Preceptor	NHLBI T32 Training Program in Sleep, Circadian and Respiratory Neurobiology, Division of Sleep Medicine, Harvard Medical School

Laboratory and Other Research Supervisory and Training Responsibilities

1997-1999 2004-2005	Supervisor for 6 undergraduate senior theses, University of Surrey, UK	80 h over 6 months each
1998	Supervisor for 2 visiting undergraduate senior theses, University of Muenster, Germany and University of Hertfordshire, UK	80 h over 6 months each
2000	Supervisor for visiting undergraduate senior thesis, Imperial College, UK	80 h over 6 months each
2000	Co-Supervisor for M.Sc. postgraduate thesis, University of Surrey, UK	60 h over 9 months

2001	Supervisor for Kleitman Summer Fellowship project, Brigham and Women's Hospital	40 h over 3 months
2002	Supervisor for 2 Division of Sleep Medicine Summer Studentship projects, Brigham and Women's Hospital	40 h over 3 months
2002-2004	Supervisor for 8 Professional Training Year visiting undergraduates, University of Surrey, UK	40 h over 12 months each
2005-2006	Supervisor for 9 projects, Summer Internship Program in Reproductive and Hormonal Risk Factors for Breast Cancer in Blind Women	20 h over 3 months each
2006	Supervisor for visiting medical undergraduate elective rotation, Warwick Medical School, UK	40 h over 3 months
2006-2007	Supervisor for 3 Professional Training Year project for visiting undergraduates, University of Surrey, UK	60 h over 9 months each
2007	Academic supervisor for two undergraduate students, Harvard College Research Program, Harvard University	20 h over 6 months each
2007	Supervisor for visiting undergraduate student, University of Toronto, Canada	80 h over 6 months
2007-2008	Internship supervisor, FAS Science Challenge Internship Program, NSBRI and Brigham and Women's Hospital	80 h over 12 months
2005-2006	Director, Summer Internship Program in Reproductive and Hormonal Risk Factors for Breast Cancer in Blind Women	Division of Sleep Medicine, Brigham and Women's Hospital
2008-2009	Advisor to MD student for Design and Conduct of Clinical Trials	Massachusetts General Hospital
2010	Supervisor for visiting medical undergraduate elective rotation, Monash University Medical Centre, Australia	40 h over 6 weeks
2011	Supervisor for Professional Training Year project for visiting undergraduates from the University of Surrey, UK	40 h over 9 months
2012	Supervisor for visiting medical undergraduate elective rotation, Warwick Medical School, UK	40 h over 6 weeks

2020-2021 Supervisor for 2 undergraduate senior theses, 40 h over 6 months each
University of Surrey, UK

Formally Mentored Harvard Medical, Dental and Graduate Students

2002-2003 Clark J. Lee, JD, MPH, CPH / Senior Law and Policy Analyst (Research Associate),
Center for Health & Homeland Security, University of Maryland, MD
Co-supervision of senior thesis, Harvard University; peer-reviewed publication in *New England Journal of Medicine*

2005-2008 Joshua J. Gooley, PhD / Assistant Professor, Duke-NUS Graduate Medical School
Singapore
Associate Preceptor for Postdoctoral Fellowship, Training Program in Sleep, Circadian
and Respiratory Neurobiology, Division of Sleep Medicine, Harvard Medical School;
peer-reviewed publications in *Current Biology*, *Science Translational Medicine*,
Journal of Neuroscience; promoted to Instructor in Medicine, Harvard Medical School
and Associate Neuroscientist, Brigham and Women's Hospital

2007 Adriana Lira-Oliver DDes / Architectural Consultant, New York
Preceptor for Postdoctoral Fellowship, Division of Sleep Medicine, Harvard Medical
School; recipient 2007 Richard Kelly Grant

2007-2008 Naila Ramji, BA, MD / Maternal-Fetal Medicine Fellow, University of Ottawa, Canada
Supervision of senior thesis, Harvard University; nominated for Hoopes' prize

2007-2009 Eliza Van Reen, PhD / CEO, Circadian Positioning Systems, Newport, RI and
Instructor in Psychiatry and Human Behavior, Brown University
Associate Preceptor for Postdoctoral Fellowship, Training Program in Sleep, Circadian
and Respiratory Neurobiology, Division of Sleep Medicine, Harvard Medical School; 3
peer-reviewed publications including *Journal of Neuroscience*

2007-2012 Melanie Rueger, PhD / Medical Science Liaison, Alnylam Pharmaceuticals, Germany
Preceptor for Postdoctoral Fellowship, Certificate Program in Sleep, Circadian and
Respiratory Neurobiology, Division of Sleep Medicine, Harvard Medical School;
promoted to Instructor in Medicine, Harvard Medical School and Associate
Neuroscientist, Brigham and Women's Hospital; peer-reviewed publication in *Journal
of Physiology*

2009-2010 Joseph T. Hull, PhD / Associate Director, Clinical Research, Supernus Pharmaceuticals,
2011-2014 Rockville, MD
Associate Preceptor for Postdoctoral Fellowship, Training Program in Sleep, Circadian
and Respiratory Neurobiology, Division of Sleep Medicine, Harvard Medical School;
peer-reviewed publication in *Journal of Neuroscience*

2010-2011 Kate E. Johnson (Crowley), PhD / Director, Babysomnia, Melbourne, Australia
Preceptor for Postdoctoral Fellowship, Division of Sleep Medicine, Brigham and
Women's Hospital and Harvard Medical School; peer-reviewed publication in *Journal
of Clinical Sleep Medicine*

2010-2011 Brian K. Abaluck, MD / Neurologist, Paoli Hospital, PA
Preceptor for Clinical Research Fellowship in Sleep Medicine, Division of Sleep

Medicine, Brigham and Women's Hospital

- 2010-2013 Erin E. Flynn-Evans, ALM, MPH, PhD / Research Psychologist, NASA Ames Research Center, CA
Preceptor for Postdoctoral Fellowship, Training Program in Sleep, Circadian and Respiratory Neurobiology, Division of Sleep Medicine, Harvard Medical School; promoted to Instructor in Medicine, Harvard Medical School and Associate Neuroscientist, Brigham and Women's Hospital
Awarded Society for Research on Biological Rhythms (SRBR) Research Merit Award; peer-reviewed publications in *Journal of the National Cancer Institute*, *Sleep*
- 2010-2015 Shadab A. Rahman, PhD / Associate Neuroscientist, Brigham and Women's Hospital; Assistant Professor of Medicine, Harvard Medical School;
Preceptor for Postdoctoral Fellowship, Training Program in Sleep, Circadian and Respiratory Neurobiology, Division of Sleep Medicine, Harvard Medical School; peer-reviewed publications in *Sleep*, *Brain*, *Behavior and Immunity*
- 2012-2015 Melissa A. St. Hilaire, PhD / Instructor, Brigham and Women's Hospital
Preceptor for Postdoctoral Fellowship, Training Program in Sleep, Circadian and Respiratory Neurobiology, Division of Sleep Medicine, Harvard Medical School; promoted to Instructor in Medicine, Harvard Medical School and Associate Biostatistician, Brigham and Women's Hospital; 3 peer-reviewed publication in *Journal of Neuroscience*, *Journal of Physiology* (2)
- 2013-2014 William Clerx /
Co-supervision of senior thesis, Harvard University
- 2018-2021 Leilah K. Grant, PhD / Instructor in Medicine, Brigham and Women's Hospital
Co-Preceptor for Postdoctoral Fellowship, Division of Sleep and Circadian Disorders, Brigham and Women's Hospital and Division of Sleep Medicine, Harvard Medical School; two peer-reviewed publications (first author) in *Frontiers in Neurology*, *Journal of Pineal Research*
- 2019-2020 Brianne A. Kent, PhD / Assistant Professor, Department of Psychology, Simon Fraser University, Canada
Preceptor for K99 Postdoctoral Fellowship, Division of Sleep and Circadian Disorders, Brigham and Women's Hospital and Division of Sleep Medicine, Harvard Medical School; peer-reviewed (second author) publication in *Frontiers in Neurology*

Other Mentored Trainees and Faculty

- 1997-1998 Laura J. Butler, BSc (Hons) /
Co-supervision of senior thesis, University of Surrey; peer-reviewed publication in *Sleep*
- 1997-1998 Ourania Kosti, PhD / Senior Program Officer, Nuclear and Radiation Studies Board, Washington DC
Co-supervision of senior thesis, University of Surrey; peer-reviewed publication in *Sleep*

- 1999-2000 Anna Zachariou, MSc / Scientific Officer, Institute of Cancer Research, UK
Co-supervision of Masters thesis, University of Surrey
- 2001-2002 Victoria L. Revell, PhD / Head of Research and Study Management, Surrey Clinical
Research Centre, University of Surrey, UK
Co-supervision of senior thesis, Imperial College; admission to graduate school
- 2002-2009 Joseph T. Hull, BS / Associate Director, Clinical Research, Supernus Pharmaceuticals,
Rockville, MD
Co-supervision of PhD; peer-reviewed publication in *Current Biology*
- 2003-2004 Marina Tsaoussoglou, BSc (Hons) / Scientist, Athens Hospital, Greece
Supervision of senior thesis and Professional Training Year projects, University of
Surrey
- 2004-2010 Erin E. Flynn-Evans, BS, RPSGT / Project Manager, Brigham and Women's Hospital
Co-supervision of PhD, University of Surrey; Associate Preceptor for Predoctoral
Fellowship, Training Program in Sleep, Circadian and Respiratory Neurobiology,
Division of Sleep Medicine, Harvard Medical School; 4 peer-reviewed publications
including *New England Journal of Medicine*, *Sleep*, *Cancer Causes Control*
- 2006-2008 Christopher S. Pechacek, SMArchS / Captain, US Air Force
Co-supervision of Masters thesis, MIT; 2 peer-reviewed publications including *Leukos*
- 2007-2008 Catherine J. Hanley, MSc /
Co-supervision of Masters thesis, University College Dublin, Eire; peer-reviewed
publication in *Journal of Neuroscience*
- 2007-2014 Ahuva Y. Segal BSc / Senior EMR Analyst, Royal Children's Hospital, Melbourne,
Australia
Co-supervision of PhD (registration withdrawn), Monash University
- 2009-2011 Julia Shekleton, DPpsych / Clinical Neuropsychologist, CAN Group, Australia
Co-supervision of PhD, Monash University; peer-reviewed publications in *Sleep*,
Journal of Clinical Sleep Medicine
- 2009-2014 Suzanne Ftouni, PhD / Post-doctoral Fellow, Circadian Therapeutics and University of
Oxford, UK
Co-supervision of PhD, Monash University; awarded Victoria Fellowship; peer-
reviewed publications in *Journal of Sleep Research*, *Journal of Biological Rhythms*
- 2011-2013 Ian C. Dunican, PhD / Director, Melius Consulting/Sleep4Performance, Australia
Co-supervision of PhD (registration withdrawn), Monash University
- 2012-2016 María L. Ámundadóttir PhD / Consultant, Iceland
Co-supervision of PhD, École Polytechnique Fédérale de Lausanne, Switzerland ;
(2014) Pre-doctoral Research Fellow, Brigham and Women's Hospital and Harvard
Medical School
- 2013 Tracey L. Sletten, PhD / Senior Research Fellow, Monash University, Australia
Preceptor for Postdoctoral Fellowship, Division of Sleep Medicine, Brigham and
Women's Hospital and Harvard Medical School

- 2013-2016 Simonne Cohen PhD / Clinical Psychologist, Sydney, Australia
Co-supervision of PhD, Monash University, Australia; peer-reviewed publications in *Scientific Reports, Autism Research*
- 2015-2017 Leslie M. Torres Ulloa, Undergraduate student, UMass Boston
Supervision of Senior Thesis
- 2015-2018 Leilah K. Grant, PhD / Instructor in Medicine. Brigham and Women's Hospital, Harvard Medical School
Co-supervision of PhD, Monash University, Australia; peer-reviewed publications in *Scientific Reports, Sleep*
- 2015-2019 Julia E. Stone, PhD / Postdoctoral Fellow, Monash University, Australia
Co-supervision of PhD, Monash University; peer-reviewed publications in *Journal of Physiology, Scientific Reports*
- 2015-2020 Saranea Ganesan, PhD student, Monash University, Australia
Co-supervision of PhD (registration withdrawn), Monash University; peer-reviewed publication in *Scientific Reports*
- 2015-2021 Laura J. Connolly, GradDipPsy, BA (Hons), PhD student, Monash University, Australia
Co-supervision of PhD, Monash University; peer-reviewed publications in *BMC Neurology, Frontiers in Neurology*
- 2017-date Lauren J. Bulfin, BSc, MNP, PhD student, Monash University, Australia
Co-supervision of PhD, Monash University
Awarded the Betty Jeffrey Award, Australian Nurses Memorial Centre
- 2017 Emma S. Giliberto, Undergraduate student, Monash University, Australia
Co-supervision of senior honors thesis, Monash University, Australia
- 2017 Amy Bender, PhD / Post-doctoral Fellow, University of Calgary, Canada
Awarded Sleep Research Society 2016-17 Mentor/Mentee Support Award
Mentor for Support Award
- 2018-2020 Lauren A. Booker, BA, GDipB.Sc, GDipPsych (Hons), MPH, PhD student, Monash University, Australia
Co-supervision of PhD, Monash University; peer-reviewed publications in *Journal of Sleep Research, Sleep*
- 2019 Vineetha Kalavally, PhD., CEng. / Associate Professor, School of Engineering, Monash University, Malaysia
Mentor for visiting sabbatical
- 2021 Nathan Howarth, BSc / Police officer, British Transport Police
Co-supervision of MSc in Health Sciences, Warwick Medical School, UK;

Formal Teaching of Peers (e.g., CME and other continuing education courses)

Those presentations below sponsored by outside entities are so noted and the sponsor is identified in parentheses.

- 2003-2007 Chautauqua National Science Foundation Short Courses for College Teachers
'Circadian Biology'

- Lecturer
8-12 College Professors; 3-day residential course; 20 h preparation, 20 h contact time
(National Science Foundation)
- 2008 Harvard Summer School course ‘Circadian Biology’
Lecturer
10 graduate students and faculty; 3-day residential course; 20 h preparation, 20 h contact time
- 2011 Harvard Medical School Department of Continuing Education and Children’s Hospital
CME course ‘Updates in Pediatric Sleep Disorders’
Lecturer
180 faculty and trainees; 2-day course; 2 h preparation, 0.5 h contact time
- 2012 Harvard Medical School Department of Continuing Education and Division of Sleep
Medicine CME course ‘Physician Work Hours, Health and Patient Safety’
Lecturer
60 physicians, health professionals and administrators; 5-day residential course; 20 h preparation, 5 lectures, 10 h contact time
***Received highest faculty rating for ‘Quality of Presentation’ and second for ‘Relevance to Practice’*
- 2012 Harvard School of Public Health Department of Continuing Education and
Occupational and Environmental Medicine Residency Program CME course ‘Sleep
and Shift Work: Optimizing Productivity and Health Management in the 24/7 Global
Economy’
Lecturer
70 faculty and administrators; 2-day course; 3 h preparation, 1 h contact time
- 2013 MediCom Worldwide Inc., CME symposium ‘Resetting the Master Body Clock:
Treatment Innovations in Non-24-Hour Disorder’. 27th Annual Meeting of the
Associated Professional Sleep Societies (APSS).
Lecturer
~150 faculty and trainees; 6 h preparation, 3 h contact time
(Vanda Pharmaceuticals Inc.)

Local Invited Presentations

No presentations below were sponsored by outside entities

- 2001 ‘Phase Response Curve for exposure to a single 1 hour 10,000 lux light pulse’
Scientific Staff Meeting Seminar
Division of Sleep Medicine, Brigham and Women’s Hospital
- 2002 ‘Phase-resetting and acute alerting effects of a one-hour pulse of bright light’ / Seminar
Neuroendocrinology Research Group, University of Surrey, UK
- 2003 ‘Spectral sensitivity of human circadian phase-shifting and long duration melatonin
suppression’ / Seminar
Neuroendocrinology Research Group, University of Surrey, UK
- 2003 ‘Phototransduction in the human circadian system’ / Seminar

- Surrey Sleep Research Centre, University of Surrey, UK
- 2003 'Phototransduction in the human circadian system' / Sleep Grand Rounds
Department of Medicine, Brigham and Women's Hospital
- 2004 'Junior Doctors' Work Hours in the US' / Seminar
Neuroendocrinology Research Group, University of Surrey, UK
- 2004 'Effects of too little of too much light – phototransduction in the human circadian system' / Invited Seminar
Sleep Showcase, University of Surrey, UK
- 2005 'Circadian photoreception in the visually impaired' / Scientific Staff Meeting Seminar
Division of Sleep Medicine, Brigham and Women's Hospital
- 2008 'Alertness, mood and performance rhythm disorders associated with circadian sleep disorders in the blind' / Scientific Staff Meeting Seminar
Division of Sleep Medicine, Brigham and Women's Hospital
- 2008 'When policy meets physiology: The challenge of reducing resident work hours'
Anesthesia and Critical Care Grand Rounds
Department of Anesthesia, Critical Care and Pain Medicine, Massachusetts General Hospital
- 2009 'When policy meets physiology: The challenge of reducing resident work hours'
Departmental Seminar
Department of Obstetrics and Gynecology, Brigham and Women's Hospital
- 2010 'Identifying and treating circadian sleep disorders presenting as insomnia' / Clinical Seminar
SleepHealth Centers, Brigham and Women's Hospital
- 2010 'Circadian rhythm sleep disorders: Principles for diagnosis and treatment' / Seminar
Center for Pediatric Sleep Disorders, Children's Hospital Boston
- 2011 'Circadian rhythm sleep disorders: Principles for diagnosis and treatment II' / Seminar
Center for Pediatric Sleep Disorders, Children's Hospital Boston
- 2012 'Nocturnal shifts and breast cancer risk' / Seminar
Breast Oncology Seminar Series, Dana Farber Cancer Institute
- 2012 'Advances in circadian photoreception' / Seminar
Center for Pediatric Sleep Disorders, Children's Hospital Boston
- 2013 'Sleep and Light' / Invited Speaker
PULSE - Population in Urban Landscape for Sustainable Built Environment consortium meeting
Harvard University
- 2013 'Circadian management of travel and jet lag' / Invited Speaker
Center for Global Health, Massachusetts General Hospital
- 2014 'Sleep, health, light and students' / Invited Speaker
University Health and Counseling Service, Northeastern University
- 2014 'Circadian rhythm disorders and their treatment in the blind' / Invited Speaker

- Sleep and Chronobiology Group, Monash University
- 2015 ‘Sleep, circadian rhythms, and light: Key components of corporate sustainability and health in the built environment’ / Invited Speaker
Harvard School of Public Health Annual CHGE Board Retreat
- 2016 ‘Datablitz’ / Invited Speaker
Sleep and Chronobiology Group, Monash University
- 2021 ‘Inter-individual differences in circadian rhythm timing and the consequences for chronomedicine’ / Invited Speaker
Exploring interfaces between Chronobiology and Sleep & Immunity and Infection, University of Surrey
- 2021 ‘Peripheral clock resetting in humans (?)’ / Invited Speaker
Chronobiology Section, University of Surrey

Report of Regional, National and International Invited Teaching and Presentations

Invited Presentations and Courses

Those presentations below sponsored by outside entities are so noted and the sponsor is identified in parentheses.

Regional

- 1998 ‘Degree of visual loss, hormone rhythms and sleep in the blind’ / Seminar
King’s Diabetes Centre, King’s College Hospital, London, UK
- 2001 ‘Cause, consequence and treatment of circadian rhythm disorders in the blind’
Seminar, Providence Research Interest Group, E.P. Bradley Hospital, Providence, RI
- 2006 ‘Eliminating extended work hours: Implications for physician health and patient safety’
Neuroscience Grand Rounds, University of Vermont College of Medicine, Burlington
- 2006 ‘Circadian rhythm sleep disorders and their treatment in the blind’ / Invited Speaker
Department of Medicine, University of Vermont College of Medicine, Burlington, VT
- 2006 ‘Circadian photoreception: More than meets the eye’ / Invited Lecture
Building Technology Program Lecture Series, Department of Architecture, MIT, Cambridge, MA
- 2006 ‘Human circadian rhythms: Basic properties and practical applications’
Invited Lecture
Takeda Pharmaceuticals East Neuroscience Group meeting, Boston, MA
(Takeda Pharmaceuticals)
- 2007 ‘Effects of extended and unusual work shifts on health and safety: Lessons from the medical profession’ / Invited Speaker
New England Water Environment Association Annual Meeting, Boston, MA
- 2008 ‘The potential for light as a non-pharmacological fatigue countermeasure’
Invited Speaker, Man Vehicle Laboratory, MIT, Cambridge, MA

- 2009 'Identifying and treating circadian sleep disorders presenting as insomnia'
Invited Speaker, 23rd Annual Conference of the North East Sleep Society, Boston, MA
- 2010 'Circadian management of travel and jet lag' / Invited Speaker
24th Annual Conference of the North East Sleep Society, Boston, MA
- 2010 'The biology of light' / Invited Speaker
2nd Acadia Night Sky Festival, Bar Harbor, ME
- 2010 'Melatonin: Diagnosis and treatment of Circadian Rhythm Disorders' / Invited Speaker
4th Annual Future of Clinical Sleep Medicine meeting, Sleep HealthCenters, Dedham, MA
- 2011 'Light as a sleepiness and circadian countermeasure in Space' / Invited Speaker
'Exploring Space Health: Benefiting Earth' Workshop, Biomedical Research Institute (BRI), Brigham and Women's Hospital, Boston, MA
- 2012 'Current Sleep Research in Occupational Medicine' / Invited Speaker
Massachusetts Sleep Society, Boston, MA
- 2012 'Workplace Sleepiness and Sleep Disorders' / Invited Speaker
New England College of Occupational and Environmental Medicine, Farmington, CT
- 2012 'If you're not alert, you're going to get hurt' / Invited Speaker
Connecticut Business and Industry Association Annual Health & Safety Conference, Farmington, CT
- 2012 'The science of sleep' / Invited Speaker
Thursday Evening Lecture Series, Brookline Adult & Community Education, Brookline, MA
- 2013 'Operation Healthy Sleep: Fatigue countermeasures in police and firefighters' / Invited Speaker
Occupational and Environmental Medicine Series, University of Connecticut Health Center, Farmington, CT
- 2013 'When policy meets physiology: The challenge of reducing resident work hours' / Invited Speaker
Medicine Grand Rounds, University of Connecticut Health Center, Farmington, CT
- 2013 'Physician work hours' / Invited Speaker
Pediatric Emergency Medicine Division, UMass Memorial Hospital, Worcester, MA
- 2013 'Sleep and circadian rhythms and their interaction with autistic spectrum disorders' / Invited Speaker
Berkshire Association of Behavior Analysis and Therapy (BCBA) Expert Speaker Series, Melmark New England, Andover, MA
- 2013 'Characterizing circadian photoreception: Studies in sighted and blind humans' Seminar, Providence Research Interest Group, E.P. Bradley Hospital, Providence, RI

- 2017 'The right light at the right time: Redesigning light for alertness, sleep and health' /
Invited Speaker
Boston Society of Architects (BSA) Committee on the Environment (COTE),
Boston, MA
- 2017 'The right light at the right time: Redesigning light for alertness, sleep and health' /
Invited Speaker
Bruner/Cott Architects and Planners, Cambridge, MA

National

- 2000 'Abnormal timing of sleep and the use of melatonin' / Invited Lecture
Royal Society of Medicine Forum on Sleep and Its Disorders, London, UK
- 2001 'Circadian rhythm disorders and their treatment in the blind' / Invited Seminar
Department of Neurology, Thomas Jefferson University, Philadelphia, PA
- 2003 'High sensitivity of the human circadian pacemaker to resetting by short wavelength
light' / Invited Seminar
National Space Biomedical Research Institute Research Update, Boston, MA
- 2005 'Eliminating extended work hours: Implications for physician health and patient safety'
Medicine Grand Rounds, Coney Island Hospital, New York, NY
- 2005 ''Wake' physiology, performance and learning' / Invited Speaker
2005 Carl T. Brighton Workshop on Orthopaedic Education, Association of Bone
and Joint Surgeons, Tampa, FL
- 2006 'Human circadian rhythms: Basic properties and practical applications'
Invited Lecture
Takeda SMART Lecture Series, Takeda Pharmaceuticals N America, Chicago, IL
(Takeda Pharmaceuticals)
- 2006 'Methodology for measuring circadian phase' / Invited Speaker
Light Research Laboratory, Thomas Jefferson University, Philadelphia, PA
- 2007 'When policy meets physiology: The challenge of reducing resident work hours'
Medicine Grand Rounds, Coney Island Hospital, New York, NY
- 2007 'Physiology and use of melatonin in the treatment of human circadian rhythm
sleep disorders' / Invited Seminar
Laboratory of Chrono-Neuroendocrine Oncology (LOCNO) Seminar Series, Bassett
Research Institute, Cooperstown, NY
- 2007 Workshop Participant, Resident Work Hours Reform, Commonwealth Fund, New
York, NY
- 2008 'Sleep and the bottom line' / Invited Webinar
(I Slept Great, LLC)
- 2008 'Circadian photoreception in humans: More than meets the eye' / Invited Seminar
Department of Biological Sciences, University of Notre Dame, South Bend, IL
- 2008 'Characteristics of light exposure necessary for development of optimal

- countermeasures to facilitate circadian adaptation and enhance alertness and cognitive performance in space' / Invited Speaker
NASA Behavioral Health and Performance Meeting, League City, TX
- 2008 'Sleep Splinter Group' / Co-Lead
NASA Behavioral Health and Performance Meeting, League City, TX
- 2008 'Phoenix Mars Lander: Prevention of problems with sleep and fatigue'
Invited Speaker
Light Research Laboratory, Thomas Jefferson University, Philadelphia, PA
- 2009 'Circadian photoreception: More than meets the eye' / Invited Seminar
Asa Gray Biological Society, Utica College, Utica, NY
- 2009 'The eye is not just for seeing: Circadian photoreception in humans'
Invited Speaker, NASA Technical Information Meeting, Kennedy Space Station, Cocoa Beach, FL
- 2010 'Light at night and human health' / Invited Speaker, Illinois Coalition for Responsible Outdoor Lighting Symposium, Chicago, IL
- 2010 'The neuroscience of light and color: How light color affects your sleep, alertness and mood' / Invited Speaker
Arts and Ideas Program, Lewis University, Romeoville, IL
- 2010 'Non-24-hour sleep-wake disorder' / Invited Speaker
Investigators Meeting, Vanda Pharmaceuticals, Washington DC
(Vanda Pharmaceuticals)
- 2010 'The role of sleep and circadian phase on crew safety, performance and psychological health during long-term analog space missions' / Invited Speaker
Behavioral Health & Performance Research Working Group, NASA, Houston, TX
- 2010 'Light and sleep' / Invited Speaker
Workshop on Light and Health, California Lighting Technology Center (CLTC), University of California, Davis, CA
- 2010 'Circadian rhythm testing' / Invited Speaker
Future of Sleep Medicine Meeting, American Academy of Sleep Medicine, Darien, IL
- 2011 'Non-visual photoreception in the human eye: Using light to counter jetlag, shiftwork and fatigue' / Invited Speaker
<http://www.dsfs.usra.edu/education/grandrounds/archive/2011/20110524/>
University of Texas Medical Branch / NASA Johnson Space Center Aerospace Medicine Grand Rounds, Houston, TX
- 2012 'Non-visual photoreception: More than meets the eye' / Invited Speaker
Carpenter Norris Consulting, New York, NY
- 2012 'Photobiology of non-visual photoreception' / Webinar
Human Centric Lighting, WA
- 2013 'Skin in space: Considerations for long-duration spaceflight' / Invited Webinar Speaker

- NSBRI Webinar, Houston, TX
- 2013 'Synchronizing education to healthy adolescent brain development' / Invited Speaker
Brain, Neurosciences and Education Special Interest Group meeting, American
Educational Research Association (AERA) meeting, San Francisco, CA
- 2013 'Non-visual photoreception: More than meets the eye' / Invited Speaker
Perkins+Will, Seattle, WA
- 2013 'Health and Light' / Invited Panelist
Healthy Body and Healthy Planet, New York, NY
(Pegasus Capital Advisors)
- 2013 'Photobiology of non-visual photoreception' / Webinar
Human Centric Lighting, WA
- 2014 'Effect of light, and light pollution, on circadian rhythms, sleep and health' / Invited
Speaker
Estee Lauder, New York, NY
(Estee Lauder)
- 2015 'Human Centric Lighting: How biology and technology can work together to improve
alertness, sleep and health' / Invited Speaker
Human Centric Lighting Conference, Seattle, WA
- 2015 'Interventions to improve sleep, alertness, and learning in schools' / Invited Speaker
Research Summit: School Buildings and Childhood Health, US Green Building
Council, Washington, D.C.
- 2015 'Advanced Technology Demonstration' (NSBRI User Panel Members) / Invited
Speaker
National Space Biomedical Research Institute, Houston, TX
- 2015 'Advanced Technology Demonstration' / Invited Speaker
National Space Biomedical Research Institute, Houston, TX
- 2016 'Research update' / Invited Speaker
Behavioral Health and Performance Program, JSC, Houston, TX
- 2016 Human Physiological Responses to Lighting / Invited Speaker
U.S. DOE Solid-State Lighting Program, U.S. DOE Roundtable: Human
Physiological Responses to Lighting, Washington, D.C.
- 2016 'How biology and technology can work together to improve alertness, sleep and health'
/ Invited Speaker
Yankee Stadium, New York, NY
(PlanLED)
- 2016 'Sleep - A Very Short Introduction: How to improve alertness, performance and health'
/ Invited Speaker
KornFerry, Sydney, Australia
(KornFerry)
- 2017 'The transformational impact of sleep on a healthy mind and body: Groundbreaking

- advances in achieving wellness through sleep’ / Invited Panel Speaker
The Carlyle Institute for Health and Wellness: A Celebration of Knowledge and Innovation Transforming Health and Wellness, Cambridge, MA
(Pegasus Capital Advisors)
- 2017 Human Physiological Responses to Lighting / Invited Speaker
U.S. DOE Solid-State Lighting Program, U.S. DOE Roundtable: Human Physiological Responses to Lighting, Washington, D.C.
- 2018 ‘How biology and new lighting technology can work together to improve alertness, sleep and health’ / Invited Speaker
Department of Design, Architecture and Building, University of Technology Sydney, Sydney
- 2018 ‘The eye is not just for seeing – the science of non-visual photoreception’ / Invited Speaker and Conference Chair
Lighting for Health and Wellbeing in the 21st Century: A workshop on the science, application, measurement, modelling and financing the non-visual benefits of light
CRC for Alertness, Safety and Productivity, Monash, Melbourne
- 2018 ‘Advances in sleep science and circadian medicine and their consequences for health’ / Invited Speaker
Innovation Seminar Series, Otsuka Pharmaceutical Development and Commercialization, Princeton, NJ
(Otsuka)
- 2018 Human Physiological Responses to Lighting / Invited Speaker
U.S. DOE Solid-State Lighting Program, U.S. DOE Roundtable: Human Physiological Responses to Lighting, Washington, D.C.
- 2018 ‘Circadian photoreception in humans: More than meets the eye’ / Invited Speaker
Departments of Ophthalmology & Pharmacology Vision Research Seminar, Emory University School of Medicine, Atlanta, GA
- 2018 ‘When policy meets physiology: The challenge of reducing resident work hours’ / Invited Speaker
Emory Eye Center Research Grand Rounds, Emory University School of Medicine, Atlanta, GA
- 2019 ‘Time to perform: Improving sports performance through sleep & circadian rhythm interventions’ / Invited Speaker
Seattle Sounders Sports Science Seminar, Seattle, WA
- 2019 Human Physiological Responses to Lighting / Invited Speaker
U.S. DOE Solid-State Lighting Program, U.S. DOE Roundtable: Human Physiological Responses to Lighting, Washington, D.C.
- 2020 ‘The right light at the right time: Redesigning light for alertness, sleep and health’ / Invited Speaker
Webinar, Dallas Architects, Dallas, TX
- 2020 ‘Biomarkers of sleep loss and circadian phase’ / Invited Science Team Member
Technical Interchange Meeting Circuits and Biomarkers of the Central Nervous System

Relating to Astronaut Performance, Houston, TX

- 2021 'Light and Health Research Updates from Harvard, Mt. Sinai, Stanford, and Thomas Jefferson' / Invited Speaker
International Illuminating Engineering Society (IES) Webinar, New York, NY
- 2021 Human Physiological Responses to Lighting / Invited Speaker
U.S. DOE Solid-State Lighting Program, U.S. DOE Roundtable: Human Physiological Responses to Lighting, Washington, D.C.

National Abstract Oral Presentations

- 1997 'Melatonin, sleep and activity rhythms in the blind'
Oral Presentation (selected abstract)
British Neuroendocrine Group Annual Meeting, Cambridge, UK
- 1998 'Melatonin is and is not a chronobiotic in the blind' / Invited Speaker
UK Clock Club, University of Surrey, UK
- 1999 'Does extraocular light exposure suppress plasma melatonin in humans?'
Invited Speaker
UK Clock Club, Institute of Psychiatry, King's College, London, UK
- 2003 'Spectral sensitivity of human circadian phase-shifting and long duration melatonin suppression' / Invited Speaker
UK Clock Club, Imperial College, London, UK
- 2008 'Spectral sensitivity of the human circadian timing system' / Invited Speaker
79th Annual Scientific Meeting of the Aerospace Medical Association, Boston, MA
- 2008 'Operation 'Healthy Sleep: A comprehensive police fatigue management program'
Invited Speaker
The National Institute of Justice Annual Conference, Arlington, VA
- 2008 'A comprehensive firefighter fatigue management program Operation Healthy Sleep'
Invited Speaker
Department of Homeland Security Assistance to Firefighters Grants Program Meeting, Washington DC
- 2009 'Characteristics of light exposure necessary for development of optimal countermeasures to facilitate circadian adaptation and enhance alertness and cognitive performance in space' / Invited Speaker
NASA Human Research Program Investigator's Workshop, League City, TX
- 2009 'Operation Healthy Sleep: An occupational screening and treatment program for obstructive sleep apnea in a city police department' / Invited Speaker
The National Institute of Justice Annual Conference, Arlington, VA
- 2009 'Circadian and neurobehavioral responses to light in humans' / Invited Speaker
American Society for Photobiology Topical Symposium, Philadelphia, PA
- 2009 'Intensity- and duration-dependent changes in the spectral sensitivity of human circadian photoreception' / Invited Speaker

- American Society for Photobiology Topical Symposium, Philadelphia, PA
- 2010 'Human circadian photoreception' / Invited Speaker
35th Meeting of the American Society for Photobiology, Providence, RI
- 2010 'Melanopsin: A new way of seeing' / Symposium Co-Chair
35th Meeting of the American Society for Photobiology, Providence, RI
- 2010 'Dissemination and uptake of the Operation Healthy Sleep program' / Invited Speaker
Department of Homeland Security Assistance to Firefighters Grants Program Meeting, Chicago, IL
- 2010 'A comprehensive firefighter fatigue management program: Operation Stay Alert' / Invited Speaker
Firefighter Cardiovascular Health & Safety Research Summit 2010, Illinois Fire Service Institute, Champaign, IL
- 2012 'Diurnal modulation in the spectral sensitivity of the acute alerting effects of light' / Invited Speaker
NASA Human Research Program Investigator's Workshop, League City, TX
- 2012 'The role of light as a circadian rhythm disorder and fatigue countermeasure in Space' / Invited Panelist
83rd Aerospace Medical Association Annual Scientific Meeting, Atlanta, GA
- 2012 'Light, sleep and circadian rhythms' / Invited Speaker
17th Annual Trainee Symposia Series, Sleep Research Society, Associated Professional Sleep Societies (APSS) meeting, Boston, MA
- 2012 'The effects of light timing, wavelength and pattern on the circadian resetting and alerting effects of light' / Invited Speaker
26th Associated Professional Sleep Societies (APSS) meeting, Boston, MA
- 2013 'International Collaboration' / Invited Speaker
18th Annual Trainee Symposia Series, Sleep Research Society, Associated Professional Sleep Societies (APSS) meeting, Baltimore, MD
***Received third highest faculty rating from 33 teaching faculty*
- 2013 'Efficacy of Tasimelteon to reset non-entrained circadian rhythms in the blind' / Invited Speaker and Symposium Chair
27th Associated Professional Sleep Societies (APSS) meeting, Baltimore, MD
- 2013 'Tasimelteon treatment entrains the circadian clock in totally blind individuals with non-24 hour circadian rhythms and significantly improves the duration and timing of sleep' / Late Breaking Abstract Invited Speaker
27th Associated Professional Sleep Societies (APSS) meeting, Baltimore, MD
- 2013 'Tasimelteon treatment entrains the circadian clock and demonstrates a clinically meaningful benefit in totally blind individuals with non-24-hour circadian rhythms' / Featured Poster Presentation Invited Speaker
95th Endocrine Society meeting ENDO 2013, San Francisco, CA
- 2013 'Causes, consequences and correction of sleepiness in healthcare workers' / Invited

Speaker

14th Annual Tennessee Perfusion Conference, Nashville, TN

- 2014 'Diagnosis and treatment of non-24 hour sleep-wake disorder in totally blind individuals' / Brown Bag Report: Challenging Cases / Invited Speaker
28th Associated Professional Sleep Societies (APSS) meeting, Minneapolis, MN
- 2014 'Light is Medicine' / Invited Speaker
27th Associated Professional Sleep Societies (APSS) meeting, Baltimore, MD
(Lighting Science Group Corporation)
- 2014 'Assessment of clinical measures in Non-24 disorder in patients entrained by tasimelteon' / Oral presentation
28th Associated Professional Sleep Societies (APSS) meeting, Minneapolis, MN
- 2014 'Lighting countermeasures for spaceflight' / Invited Speaker
NASA/NSBRI HRP Workshop Sleep on Earth and in Space: Risk factors, health and performance outcomes, and countermeasures, Houston, TX
- 2014 'Tuning the spectrum: Light, health, and the pursuit of happiness' / Invited Speaker
2014 DOE Solid-state lighting market development workshop, Detroit, MI
- 2015 'Tuning the spectrum: Light, health and productivity' / Invited Speaker
2015 Portland Lights, Portland, OR
- 2015 'How to measure and implement the health benefits of light' / Invited Speaker
2015 Portland Lights, Portland, OR
- 2016 'How Lighting Affects Student Performance in the Classroom' / Invited Speaker
95th Wisconsin State Education Conference, Milwaukee, WI
(Midwest Lighting Institute)

International

- 1999 'Causes, consequences and treatment of circadian rhythm disorders in the blind'
Invited Seminar
Circadian, Neuroendocrine and Sleep Disorders Section, Division of Endocrinology,
Brigham and Women's Hospital, Boston, USA
- 2000 'Effects of melatonin on human free running rhythms' / Invited Speaker
Gordon Conference on Pineal Cell Biology, Oxford, UK
- 2001 'Human circadian physiology and behavior in the absence of photoreception'
Invited Speaker
Gordon Conference on Chronobiology, Newport, USA
- 2004 Invited speaker, European Dana Alliance for the Brain, The Dana Centre, London, UK
- 2004 'Circadian rhythms in blind women' / Invited speaker
NIEHS Circadian Disruption and Breast Cancer Meeting, Chapel Hill, USA
- 2004 'Phototransduction' / Symposium Chair
Gordon Conference on Pineal Cell Biology, Oxford, UK
- 2005 'Circadian and sleep-wake dependent control of alertness, mood and performance in

- the blind' / Invited speaker
Fatigue, Sleep and Biological Clocks International Conference, London, UK
- 2005 'Eliminating extended work hours: Implications for sleep and fatigue'
Invited speaker
Royal College of Physicians Working Group on Nocturnal Shiftwork, London, UK
- 2007 'Junior doctors working hours and medical errors: The Harvard Medical School experience'
Medicine Grand Rounds, Warwick Medical School, UK
- 2007 'Spectral sensitivity of circadian, neuroendocrine and neurobehavioral effects of light' / Keynote Speaker
2nd International Symposium on the Design of Artificial Environments, Fukuoka, Japan
- 2007 'Introduction to the Circadian Physiology Program' / Workshop Participant
Lighting Research Program, Japan
- 2007 'Extended work shifts of medical residents: Consequences and countermeasures'
Invited Speaker
National Institute of Occupational Safety and Health, Japan
- 2007 'Sleep disorders detection and treatment program in a police department'
Invited Speaker, University of Tsukuba, Tsukuba, Japan
- 2008 'When policy meets physiology: The challenge of reducing sleepiness in occupational settings' / Invited Seminar
Department of Chronobiology, INSERM, Lyon, France
- 2008 'The role of photic and non-photoc time cues on circadian organisation in humans'
Invited Speaker
Gordon Conference on Pineal Cell Biology, Barga, Italy
- 2008 'The eye is not just for seeing: Circadian photoreception in humans'
Invited Seminar
Department of Psychology, University of Montreal, Canada
- 2009 'Light and the Circadian System - State of the Art & Applications to Design'
Invited speaker, Lightfair International, New York, USA
- 2009 'Circadian photoreception in humans: More than meets the eye' / Invited Speaker
Philips Lighting, Eindhoven, The Netherlands
(Philips Lighting)
- 2009 'Circadian phase setting effects of melatonin in free-living people' / Invited Speaker
Circadian Disruption & Cancer, New York Academy of Sciences, New York, USA
- 2009 'The European Working Time Directive and Junior Doctors: Safe implementation of a 48-hour work week' / Invited Speaker
19th International Symposium on Shiftwork and Working Time, Venice, Italy
- 2009 'Measuring circadian rhythms', Master Workshop, School of Psychology and Psychiatry, Monash University, Melbourne, Australia

- 2009 'Methodologies in chronobiology', Workshop, Australian Centre for Chronobiology, Endocrinology, and Sleep Science (ACCESS), Woolcock Institute of Medical Research, Sydney, Australia
- 2009 'When policy meets physiology: The challenges in reforming doctors' work hours' / Invited Speaker
Monash Sleep Network / Australasian Sleep Society Public Lecture, Melbourne, Australia
- 2009 'Dealing with jet-lag and other sleep disturbances' / Invited Speaker
Harvard Club of Australia - Victoria, Melbourne, Australia
- 2009 'Effects of extended work hours on ICU patient safety and physician health' / Invited Speaker, ICU Consultant's meeting, Alfred Hospital, Melbourne, Australia
- 2009 'When policy meets physiology: The challenges in reforming doctors' work hours' / Invited Speaker
Discipline of Sleep Medicine, University of Sydney / Woolcock Institute, Sydney, Australia
- 2009 'Review of key objectives in chronobiology research, services and policy internationally' / Invited Speaker
Centre for Integrated Research and Understanding of Sleep (CIRUS), Woolcock Institute, Sydney, Australia
- 2009 'A novel photoreceptor in the human eye: Circadian, neuroendocrine and neurobehavioural responses to light' / Invited Speaker
International Graduate School for Neuroscience, Ruhr University, Bochum, Germany
- 2010 'Pathophysiology of circadian desynchrony' / Invited Speaker
International Space Station Circadian Management Subgroup, Multilateral Medical Operations Panel (MMOP) meeting
Institute of Biomedical Problems, Russian Academy of Sciences, Moscow, Russia
- 2010 'Countermeasures for circadian desynchrony' / Invited Speaker
International Space Station Circadian Management Subgroup, Multilateral Medical Operations Panel (MMOP) meeting
Institute of Biomedical Problems, Russian Academy of Sciences, Moscow, Russia
- 2010 'Circadian rhythms and melatonin: A brief review' / Invited Speaker
Icelandic Heart Association project meeting, Reykjavik, Iceland
- 2011 'Extended shift work: Health and Safety issues' / Invited Speaker
Labour Relations Seminar, Ontario Association of Fire Chiefs, Toronto, Canada
- 2011 '24-hour shifts: Health and Safety issues' / Invited Speaker
24 Hour Shift in Midsize Departments Seminar, Ontario Association of Fire Chiefs, Toronto, Canada
- 2011 'Light applications for sleep, sleepiness and sleep disorders' / Invited Speaker
Department of Architecture, Monash University, Australia
- 2011 'Fatigue management in occupational settings' / Plenary Speaker

- 8th International Conference on Managing Fatigue in Transportation, Resources & Health, Fremantle, Australia
- 2011 ‘Challenges for fatigue risk management in healthcare’ / Plenary Speaker, Chair
8th International Conference on Managing Fatigue in Transportation, Resources & Health, Fremantle, Australia
- 2011 ‘Sleep at Harvard’ / Invited Speaker
Woolcock Institute of Medical Research, Sydney, Australia
- 2011 ‘Catalysts & Barriers to International Collaboration’ / Invited Panelist
International Collaboration on Analog Utilization Workshop, NASA, Houston TX
- 2012 ‘Causes, consequences and correction of sleepiness in the workplace’ / Invited Speaker
Rio Tinto Fatigue Management Improvement Workshop, Montreal, Canada
(Rio Tinto)
- 2012 ‘Municipal Risks & Liabilities of Shift Schedules’ / Invited Speaker
2012 Emergency Services Labour Forum, Emergency Services Steering Committee, Toronto, Canada
- 2013 ‘The role of light as a circadian rhythm disorder and fatigue countermeasure in Space’ / Invited Speaker
Human Research Program Investigators’ Workshop, NASA, Galveston TX
- 2013 ‘The benefits of light: More than meets the eye’ / Invited Speaker
Photon Pod Symposium, London Design Festival, London, UK
- 2014 ‘Assessing sleep, circadian rhythms, performance, health and safety in 50 expeditioners overwintering in Antarctica’ / Invited Speaker
BHP Working Group, Human Research Program, NASA, Galveston TX
- 2014 ‘The ISS Dynamic Lighting Schedule: An In-Flight Lighting Countermeasure to Facilitate Circadian Adaptation, Improve Sleep and Enhance Alertness and Performance on the International Space Station’ / Invited Speaker
Human Research Program Investigators’ Workshop, NASA, Galveston TX
- 2014 ‘Smart lighting: Advances in circadian photoreception’ / Invited Webinar
<http://www.sleep.org.au/education/webinars/smart-lighting-advances-in-circadian-photoreception>
<https://youtu.be/MP4C41EbCb4>
Webinar Series, Australasian Sleep Association, Australia
- 2014 ‘The Wellness Revolution: The next driver of the lighting industry’
Invited panelist, Lightfair International, Las Vegas, USA
(Delos Living LLC)
- 2014 ‘More than meets the eye: Introduction to non-visual photoreception’ and ‘Applications of smart lighting: Healthcare, schools and shift workers’ / Invited Speaker
Workshop for Circadian Lighting in Healthcare & Education, London, UK
(Carbon Limiting Technologies Ltd, UK on behalf of PhotonStar LED Group PLC)
- 2015 ‘Medical applications for tunable white light’ / Invited speaker

- Lightfair International, New York, USA
- 2015 'Melatonin analogues for the treatment of circadian sleep disorders' / Invited Speaker
FASEB Summer Research Conference 'Melatonin Biology: Actions and Therapeutics', Lisbon, Portugal
- 2015 'Sleep and recovery' / Invited Speaker
Hints Academy, Helsinki, Finland
(Hints Performance AG)
- 2015 'Tasimelteon for the treatment of non-24-hour sleep-wake rhythm disorder in the totally blind' / Invited speaker
Australasian Chronobiology Society, Melbourne, Australia
- 2015 'Human circadian photoreception and introduction to applications' / Invited Speaker
Let there be Light: Circadian Lighting, Health, and the WELL Building Standard (LD10), Greenbuild International Conference and Expo, Washington, D.C.
(US Green Building Council)
- 2016 'Entraining the circadian clock in totally blind patients' / Invited speaker
The therapeutic use of melatonin and melatonin agonists: Past discoveries, present practice and future directions, London, UK
(Vanda Pharmaceuticals Inc.)
- 2016 'The eye is not just for seeing: Circadian photoreception in humans' / Invited speaker
Neuroscience Research Australia Invited Seminar Series, NeuRA, Sydney, Australia
- 2017 'Circadian rhythms and lighting in space' / Invited Speaker and Workshop participant
Space Medicine: Terrestrial Applications for Human Health Performance and Longevity, Bellagio II, International scientific summit ASMA 2017, Moltrasio, Italy
- 2017 'Non-24-hour sleep-wake rhythm disorder in visually impaired people' / Keynote Speaker
When the (biological) clock ticks out of time, 1st Basel Symposium on Circadian Rhythm Disorders, Basel, Switzerland
- 2017 'The eye is not just for seeing: How light affects alertness, sleep and circadian rhythms' / Invited Speaker
DIVA Day 2017, University of California Berkeley, USA
- 2017 'The right light at the right time: Redesigning light for alertness, sleep and health' / Invited Speaker
Greenbuild International Conference and Expo, Boston, USA
- 2018 'The eye is not just for seeing: How light affects alertness, sleep and circadian rhythms' / Invited Speaker
<https://www.youtube.com/watch?v=HvsJyxLXblk>
Chartered Institution of Building Services Engineers, London, UK
- 2018 'The importance of measuring circadian phase' / Invited Speaker
Translational & Experimental Medicine (TEM) Seminar, University of Warwick, Coventry, UK

- 2018 'The right light at the right time: redesigning light for alertness, sleep and health' /
Keynote Speaker
IES Annual Conference, Boston, MA
- 2018 'How to sleep your way to health and wellness' / Invited Panel Speaker
The Carlyle Institute for Health and Wellness: A Celebration of Knowledge and
Innovation Transforming Health and Wellness, Monaco
(Mental Workout)
- 2018 'JetLag is history' / Invited Panel Speaker
Web Summit, Lisbon, Portugal
(Mental Workout)
- 2018 'Sleep: A Very Short Introduction' / Invited Speaker
Ineos CEO Retreat, Monaco
(Ineos)
- 2019 'Health aspects of light pollution on humans' / Invited Speaker
Signify Lighting University webinar
- 2019 'How light or lack of light affects circadian rhythms' / Plenary Speaker
Celebration of Prof Charles A. Czeisler, Boston, USA
- 2020 'Measuring circadian rhythms in humans' / Invited Lecturer (online)
2020 International Chronobiology Summer School, Smith University, Northampton,
USA
- 2020 'Indoor light and circadian rhythms' / Invited Lecturer (online)
Workshop: The Great Indoors: Environmental Quality, Health and Wellbeing in a
Quarantining Society, University of Toronto, Canada
- 2020 'How to stop the lighting harming your kids' / Invited Workshop participant (online)
Age of Light Innovations Group, London, UK
- 2020 'Illuminating space' / Invited speaker (online)
NASA Space Center Houston/UTMB Thought Leader Series, Houston, USA
<https://spacecenter.org/event/thought-leader-series/>
- 2021 'Non-visual effects of light and its application in architecture' / Invited Speaker
Society for Light Treatment and Biological Rhythms (SLTBR) Webinar
- 2021 'Recommendations for melanopic lighting design' / Invited Speaker
Society of Light and Lighting (SLL) Webinar
- 2021 'The right light at the right time: redesigning light for alertness, sleep and health' /
Invited Speaker
Bloxhib Workshop Daylight Impact on Humans Webinar
(Lys)
- 2021 'Models and data for real life sleep restriction, performance and circadian
rhythmicity' / Invited Speaker
Workshop - Multilevel Dynamics of Human and Animal Sleep: Mathematical
Models Meet Data, Institute of Advanced Studies, University of Surrey, UK

- 2021 'The importance of light for human well-being' / Keynote Speaker
 Lysets Dag 2021, Danish Center for Lighting Annual Conference

International Abstract Oral Presentations

- 1996 'Assessment of 6-sulphatoxymelatonin, sleep and activity rhythms in visually impaired subjects' / Oral Presentation (selected abstract)
 World Conference on Chronobiology and Chronotherapeutics, Ferrara, Italy
- 1997 'Changes in sleep in relation to circadian phase'
 Oral Presentation (selected abstract)
 International Congress on Chronobiology, Paris, France
- 1998 'Effect of melatonin on circadian sleep disorders in the blind'
 Oral Presentation (selected abstract)
 6th Meeting of the Society for Research on Biological Rhythms, Amelia Island, USA
- 1999 'Melatonin entrains free-running blind subjects in a phase-dependent manner'
 Oral Presentation (selected abstract)
 8th Colloquium of the European Pineal Society, Tours, France
- 2000 'Light and circadian rhythms in the blind' / Invited Speaker
 13th International Congress on Photobiology, San Francisco, USA
- 2000 'Chronobiological photoreceptors in mice and humans' / Symposium Co-Chair
 13th International Congress on Photobiology, San Francisco, USA
- 2000 'Entrainment of totally blind subjects: Photic or non-photic?'
 Oral Presentation (selected abstract)
 7th Meeting of the Society for Research on Biological Rhythms, Amelia Island, USA
- 2001 'Circadian and sleep-wake dependent control of alertness, mood and performance in field studies of blind subjects' / Oral Presentation (selected abstract)
 15th Meeting of the Associated Professional Sleep Societies, Chicago, USA
- 2002 Invited Workshop Participant
 8th Meeting of the Society for Research in Biological Rhythms, Amelia Island, USA
- 2002 'Circadian, endocrine and sleep monitoring for human studies'
 Chair, Techniques Tutorial
 8th meeting of the Society for Research in Biological Rhythms, Amelia Island, USA
- 2002 'Phototransduction in the human circadian system' / Invited Speaker
 30th Meeting of the American Society for Photobiology, Quebec City, Canada
- 2002 'Persistence of circadian modulation of sleep in free-running blind subjects not entrained by 5mg melatonin' / Oral Presentation (selected abstract)
 16th Congress of the European Sleep Research Society, Reykjavik, Iceland
- 2002 'Light and human circadian regulation' / Invited Speaker

- 5th International Meeting of the Lighting Research Organization, Orlando, USA
- 2003 'Properties of photic circadian phase resetting in humans' / Invited Speaker
31st Meeting of the American Society for Photobiology, Baltimore, USA
- 2003 'Effects of light on human circadian rhythms' / Invited speaker
Ecology of the Night International Symposium, Muskoka, Canada
- 2004 'Light and human circadian regulation' / Invited speaker
CIE International Symposium on Light and Health, Vienna, Austria
- 2004 'Wavelength-dependent effects of light on vigilance and performance'
Invited speaker
17th Congress of European Sleep Research Society, Prague, Czech Republic
- 2005 'Research to improve police performance by managing officer fatigue' / Invited speaker, 14th World Congress of Criminology, Philadelphia, USA
- 2006 'Human circadian photoreception: From behavior to receptors' / Invited speaker
39th Winter Conference on Brain Research, Steamboat Springs, USA
- 2006 'Photic and non-photic regulation of circadian rhythms in the blind' / Invited speaker
20th Meeting of the Associated Professional Sleep Societies, Salt Lake City, USA
- 2006 'Spectral sensitivity for long-duration light exposure on human circadian photoreception' / Invited Speaker
18th Meeting of the Society for Light Treatment and Biological Rhythms, Québec City, Canada
- 2006 'Photoreception for human circadian rhythm regulation and other brain functions'
Invited Speaker
2nd CIE International Symposium on Light and Health, Ottawa, Canada
- 2007 'Photoreception for human circadian rhythm regulation and other brain functions'
Invited Speaker
40th Winter Conference on Brain Research, Snowmass, USA
- 2007 'US resident work hours limits adversely impact patient safety and resident health'
Invited Speaker
18th International Symposium on Shiftwork and Working Time, Yeppoon, Australia
- 2007 'Acute stimulating effects of short-wavelength light exposure' / Symposium Chair
5th Congress of the World Federation of Sleep Research and Sleep Medicine, Cairns, Australia
- 2007 'Light environment' / Symposium Co-Chair
2nd International Symposium on the Design of Artificial Environments, Fukuoka, Japan
- 2008 'Circadian, neuroendocrine and neurobehavioral responses to light in humans'
Invited Speaker
41st Winter Conference on Brain Research, Snowbird, USA
- 2008 'Intensity- and duration-dependent changes in the spectral sensitivity of human circadian photoreception' / Invited Speaker

- 11th Meeting of the Society for Research in Biological Rhythms, Destin, USA
- 2008 'Short- and long-term research program planning' / Invited Seminar
Trainee Development Day, 11th meeting of the Society for Research in Biological Rhythms, Destin, USA
- 2008 'Assessment of sleepiness in field-based research' / Invited Seminar
Postgraduate Course, 22nd Meeting of the Associated Professional Sleep Societies, Baltimore, USA
- 2008 'No time for sleep: The causes and consequences of sleep and circadian rhythm disorders in Space' / Invited Speaker
29th Annual International Gravitational Physiology Meeting, Angers, France
- 2008 'Effect of gravity on biological rhythms and sleep' / Symposium Co-Chair
29th Annual International Gravitational Physiology Meeting, Angers, France
- 2008 'Effects of photic and non-photic stimuli on melatonin' / Invited Speaker
FASEB Summer Research Conference 'Melatonin receptors: Actions and therapeutics', Snowmass, USA
- 2008 'Therapeutic role of new melatonin receptor agonists' / Symposium Chair
FASEB Summer Research Conference 'Melatonin receptors: Actions and therapeutics', Snowmass, USA
- 2009 'Operation Healthy Sleep: An occupational screening and treatment program for obstructive sleep apnea in a city police department' / Invited Speaker
Track B: Health-Related/Pharmacological Issues, 2009 International Conference on Fatigue Management in Transportation Operations, Boston, USA
- 2009 'Operation Healthy Sleep: An occupational screening and treatment program for obstructive sleep apnea in a city police department' / Invited Speaker
Track F: Evaluation of Fatigue Risk Management Systems, 2009 International Conference on Fatigue Management in Transportation Operations, Boston, USA
- 2009 'Occupational Fatigue Management Programs: Assessing sleep, sleepiness and sleep disorders in the real world' / Invited Speaker
4th Meeting of the Canadian Sleep Society, Toronto, Canada
- 2009 'Circadian photoreception in humans: More than meets the eye' / Invited Speaker
3rd VELUX Daylight Symposium, Rotterdam, The Netherlands (Velux)
- 2009 'Short-wavelength sensitivity for the direct effects of light on alertness and waking EEG in humans' / Invited Speaker
23rd Meeting of the Associated Professional Sleep Societies, Seattle, USA
- 2009 'Cardio-Pulmonary Chronobiology' / Symposium Chair
23rd Meeting of the Associated Professional Sleep Societies, Seattle, USA
- 2009 'Light pollution and sleep' / Invited Speaker <http://vimeo.com/9299326>
9th European Symposium for the Protection of the Night Sky, Armagh, UK
- 2009 'Role of melatonin in the diagnosis and treatment of circadian rhythm sleep disorders

- in the blind' / Plenary Speaker
21st Meeting of the Australasian Sleep Association, Melbourne, Australia
- 2009 'Spectral sensitivity and spectral adaption of the human circadian timing system'
Invited Speaker
21st Meeting of the Australasian Sleep Association, Melbourne, Australia
- 2010 'Human circadian photoreception' / Invited Speaker
ISER 2010 XIX Biennial Meeting of the International Society for Eye Research,
Montreal, Canada
- 2010 'Circadian, neuroendocrine and neurobehavioral effects of light in humans' /
Symposium Co-Chair
ISER 2010 XIX Biennial Meeting of the International Society for Eye Research,
Montreal, Canada
- 2010 'Sleep, Sleepiness and Sleep Disorders' / Invited Speaker
7th Emergency Social Services Association (ESSA) Conference, Birmingham, UK
(Emergency Social Services Association)
- 2014 'Efficacy of tasimelteon treatment in totally blind individuals with non-24-hour sleep-
wake disorder' / Invited Speaker
14th meeting of the Society for Research in Biological Rhythms, Big Sky, USA
- 2016 Modeling neurocognitive decline and recovery during repeated cycles of extended
sleep and chronic sleep deficiency / Invited speaker
Australasian Chronobiology Society, Adelaide, Australia
- 2016 'Applying circadian and sleep medicine principles to improve occupational
performance' / Invited speaker
Australasian Sleep Association, Adelaide, Australia
- 2016 'Resetting peripheral circadian rhythms' / Invited speaker
Australasian Sleep Association, Adelaide, Australia
- 2016 'Circadian shifting' in motorsports – international travel and 24 hour events' / Invited
Speaker
2016 International Council of Motorsport Sciences (ICMS) Annual Congress
Indianapolis, USA
- 2017 'Development and testing of biomarkers to determine individual astronauts'
vulnerabilities to behavioral health disruptions' / Invited Speaker
Human Research Program Investigators' Workshop, NASA, Galveston TX
- 2017 'Light-dependent effects on alertness and cognitive performance' / Invited Speaker
9th DIN, Berlin, Germany
- 2017 'The impact of light on neurobehavioral performance' / Invited Speaker
29th Annual Meeting of the Society for Light Treatment and Biological Rhythms
(SLTBR), Berlin, Germany
- 2017 'Human Needs in the Built Environment' / Invited Speaker
International Dark-Sky Association 2017 Annual General Meeting & Conference:
Reclaiming the Night, Boston, USA

- 2018 ‘What we know about the effects of light on humans’ / Invited Speaker
IES Research Symposium: Light + human health, Atlanta, USA
- 2018 ‘Developing metrics for light and health applications’ / Invited Speaker
IES Research Symposium: Light + human health, Atlanta, USA
- 2019 ‘Time-based dynamics of non-visual effects of light in humans: The importance of
exposure duration’ / Invited Speaker
XVI European Biological Rhythms Society (EBRS) Congress, Lyon, France
- 2020 ‘Development and testing of biomarkers to determine individual astronauts’
vulnerabilities to behavioral health disruptions’ / Invited Speaker
Human Research Program Investigators’ Workshop, NASA, Galveston, USA
- 2020 ‘Lighting protocols for exploration – HERA campaign’ / Invited Speaker
Human Research Program Investigators’ Workshop, NASA, Galveston, USA
- 2021 ‘Development and testing of biomarkers to determine individual astronauts’
vulnerabilities to behavioral health disruptions’ / Invited Speaker
Human Research Program Investigators’ Workshop, NASA (online)
- 2021 ‘Lighting protocols for exploration – HERA campaign’ / Invited Speaker
Human Research Program Investigators’ Workshop, NASA (online)

Report of Clinical Activities and Innovations

Clinical Innovations

- 2000 Lead author of investigator-initiated trial to demonstrate for the first time that
daily melatonin treatment could entrain the circadian clock in totally blind
patients with non-24-hour sleep-wake disorder
- 2010-2014 Provided initial ideas and key support for development and implementation of a
Clinical Practice Guideline, the ‘NASA Implementation Plan for Circadian
Desynchrony’ with Smith L. Johnston, M.D., NASA Flight Surgeon
- 2014 Principal Investigator of clinical trials supporting approval of a new FDA- and
EMA-approved drug, Hetlioz™, a dual melatonin receptor agonist, to treat non-
24-hour sleep-wake disorder in totally blind patients, and the first drug approved
by the FDA to treat a circadian rhythm sleep disorder
- 2016 Development and publication of the first validated questionnaire to screen for
risk of Non-24-Hour Sleep-Wake Rhythm Disorder in the blind
- 2021 Provided guidelines for non-visual lighting to NASA for Galaxy and other space
habitats. “Gateway Computer Human Interfaces Interior Lighting Requirements,
Computer Human Interfaces Team Imagery and Lighting, NASA/EV3, February
24, 2021 (L2-CHI-0127 Physiological effects of light (alertness, sleep, circadian
entrainment and circadian resetting)”

Report of Technological and Other Scientific Innovations

- US Patent ‘Method for modifying or resetting the circadian cycle using short wavelength light’ (Publication No. US20060106437A1); 2005. Abandoned
Czeisler CA, **Lockley SW**, Kronauer RE, Brainard GC.
Brigham and Women’s Hospital, Inc.
The patent cover discoveries in the efficacy of short-wavelength light for resetting the circadian pacemaker and alerting the brain as a potential countermeasure for use in clinical and occupational settings to treat circadian rhythm sleep disorders or acute sleepiness.
- US Patent ‘Systems and methods for determining and/or controlling sleep quality’ (Application No. 62/233,030); 2015. Abandoned
Cedeno Laurent JG, **Lockley SW**, Spengler JD
Harvard University and Brigham and Women’s Hospital, Inc.
The patent cover discoveries in the use of environmental monitoring to assess sleep timing, duration and quality.
- US Patent ‘Method and system for generating and providing notifications for a circadian shift protocol’ (Publication No. US20190366032A1); 2019. Pending
Lockley S, Hanna T, Ravn J, Beyer-Clausen M, Maxik F
Timeshifter Inc.
- US Patent ‘Display screen or portion thereof with graphical user interface’ (Publication No. US USD897362S1); 2020. Published.
Lockley S, Hanna T, Ravn J, Beyer-Clausen M
Timeshifter Inc.
- US Patent ‘Method to shift circadian rhythm responsive to future therapy’ (US 20210162164); 2021. Pending.
Lockley S, Hanna T, Ravn J, Beyer-Clausen M, Maxik F
Timeshifter Inc.

Report of Education of Patients and Service to the Community

Activities

Those presentations below sponsored by outside entities are so noted and the sponsor is identified in parentheses.

- 2002 ‘The impact of blindness on sleep disturbance’ / Invited Speaker
41st Annual Convention of the American Council for the Blind, Houston, TX
- 2003 Expert Testimony
Local 1992, International Association of Firefighters and Town of North Attleboro arbitration (Joint Labor Management Committee – Case No. 02-21F)
- 2003 ‘Sleep study update’ / Invited Speaker
42nd Annual Convention of the American Council for the Blind, Pittsburgh, PA
- 2003 ‘Sleep and circadian rhythm disorders in the visually impaired’

- Invited Speaker, Annual Meeting of the Bay State Council for the Blind, Boston, MA
- 2005 'Nationwide survey of breast cancer risk in blind women' / Invited Speaker
44th Annual Convention of the American Council for the Blind, Las Vegas, NV
- 2005 Sleep and health information booth host
44th Annual Convention of the American Council for the Blind, Las Vegas, NV
- 2005 'Nationwide survey of breast cancer risk in blind women' / Invited Workshop
65th Annual Convention of the National Federation of the Blind, Louisville, LA
- 2005 Sleep and health information booth host
65th Annual Convention of the National Federation of the Blind, Louisville, LA
- 2007 Invited speaker, Sleep Panel, Community Health Initiative, Harvard University
Discussion panel on sleep health for undergraduate students
- 2007 Invited speaker, 'Pajama Party', Dunster House, Harvard University Health Services
<http://www.theharvardcrimson.com/article/2007/4/10/hms-prof-discusses-sleep-its-probably/>
Discussion panel on sleep health for undergraduate students
- 2008 Expert Testimony
The City of New York and Patrolmen's Benevolent Association arbitration
(New York State Public Employment Case No. IA 2006-24; M 2006-093)
- 2008- Sleep and health information booth host (2008) / organizer (2009)
- 2009 United Airlines Wellness Day, Logan Airport, Boston, MA
- 2010 'Non 24-hour sleep wake disorder' / Seminar
70th Annual Convention of the National Federation of the Blind, Dallas, TX
(Vanda Pharmaceuticals)
- 2011 'The City Dark' by Ian Cheney, Wicked Delicate Films, USA
Maine Starlight Festival public film screening and Q&A session
- 2011 Expert Testimony
Interest arbitration between the City of Airdrie and IAFF Local 4778 Airdrie
Professional Firefighters Association
- 2012 Expert Testimony
Interest arbitration between the Town of Ajax and the IAFF 1092 Ajax Professional
Firefighters Association
- 2012 Expert Testimony
Civil action Kevin Faile et al., *versus* Lancaster County, South Carolina
(District of South Carolina, Rock Hill Division, Civil Action No. 0:10-cv-2809-CMC)
- 2012 Expert Testimony
Interest arbitration between the Town of Fredericton and IAFF Local 1053
Fredericton Professional Firefighters Association
- 2013 'Diagnosis and management of non-24-hour sleep-wake disorder' / Invited Speaker
73rd Annual Convention of the National Federation of the Blind, Orlando, FL
(Vanda Pharmaceuticals Inc.)

- 2013 'Diagnosis and management of non-24-hour sleep-wake disorder' / Invited Speaker
52nd Annual Convention of the American Council for the Blind, Columbus, OH
(Vanda Pharmaceuticals Inc.)
- 2013 'Diagnosis and management of non-24-hour sleep-wake disorder' / Invited Speaker
Blinded Veterans Association meeting, Spokane, WA
(Vanda Pharmaceuticals Inc.)
- 2013- Expert Testimony
2014 Interest arbitration between the City of Burlington and the IAFF Local 2313
Burlington Professional Firefighters Association
- 2014 Expert Testimony
Interest arbitration between the City of Brantford and the IAFF Local 460 Brantford
Professional Firefighters Association
- 2014 Expert Testimony
Interest arbitration between the City of St. Catherines and the IAFF Local 485 St
Catherines Professional Firefighters Association
- 2015- Expert Testimony
2016 Civil action David McGee et al., versus Pallito, Vermont Department of Corrections
(Case No. 1:04-cv-335-jgm)
- 2018- Expert Testimony
date Vanda Pharmaceuticals Inc., versus Teva Pharmaceuticals USA, Inc. et al., (Case No.
18-651, 18-689, 18-690 (CFC))
- 2021 Expert Testimony
Civil action In the Matter of the Appeal of Fischer Studio Building Condominium
Owners Association (Seattle Hearing Examiner File MUP-21-004)

Educational Material for Patients and the Lay Community

Books, monographs, articles and presentations in other media

- 1997 'Circadian rhythm and sleep disorders in the blind', Drive Time', BBC Radio 5 Live,
UK
Interviewed for live radio program
- 1997 'Circadian rhythm and sleep disorders in the blind', BBC Radio Newcastle, UK
Interviewed for radio program
- 1997 'Circadian rhythm and sleep disorders in the blind', 'Outlook' BBC World Service
Interviewed for radio program
- 1997 'Circadian rhythm and sleep disorders in the blind', BBC Radio County Sound, UK
Interviewed for radio program
- 1999 'Raging Hormones - Melatonin', BBC Radio 4, UK

- Interviewed for radio program
- 2000 'Effect of light and circadian rhythms', Discovery Channel, ITN, UK
Interviewed for television feature
- 2002 'Sleep disorders in the blind'
Speaker on American Council for the Blind radio show 'Blind Line'
- 2007 'Lighting and Health', National Research Council of Canada <http://www.nrc-cnrc.gc.ca/eng/multimedia/podcasts-lighting-health.html>
Interviewed for podcast
- 2008 'Cracking the Colour Code' by Hugh Piper, Electric Pictures, Australia
Featured in documentary
- 2010 Adler Night and Day by Katie Peterson, Adler Planetarium and Astronomy Museum, http://www.adlerpodcast.com/nightandday/2010/episode_83_031610.mp3
Interviewed for podcast
- 2010 'Biology of light', *WVOM-FM Radio*, Bangor, ME
Interviewed for live radio program
- 2011 'Light and sleep', PM Program, *BBC Radio 4*, London, 1/13/11
Interviewed for live radio program
- 2011 'Light and sleep' by Kristi King, *WTOP News*, Washington DC, 1/14/11
Interviewed for radio program
- 2011 'The City Dark' by Ian Cheney, Wicked Delicate Films, USA
<http://www.thecitydark.com/>
Featured in documentary, Broadcast on PBS, 7/5/12
<http://www.pbs.org/pov/citydark/>
- 2011 'Karen Pauls, CBC Radio, Manitoba, Canada
Interviewed for radio program
- 2012 **Lockley SW**, Foster RG. *Sleep: A Very Short Introduction*. Oxford, UK: Oxford University Press; 2012. ISBN13: 9780199587858; ISBN10: 019958785X. Available in English, Japanese, Arabic, Dutch. Part of a 400+book series on common topics.
- 2012 'Electric Light: Dawn of a New Era' by Boettcher Media Group, USA
<https://www.youtube.com/watch?v=C0woLhghCb4>
Featured in documentary
- 2012 'Jetlag', Breakfast Program, *ABC Perth radio*, Australia, 8/24/12
Interviewed for radio program
- 2012 'Saving daylight', *Huffington Post*, 11/2/12
<http://live.huffingtonpost.com/r/segment/5061e22978c90a7ce5000219>
Participated in liveblog
- 2012 'Lights Out!' CBC Nature of Things with David Suzuki by Markham Street Films Inc., 12/6/12
Featured in documentary
- 2012 'A medical system of sleep deprivation' by Ibbby Caputo, WGBH, 12/21/12

- <http://www.wgbhnews.org/post/medical-system-sleep-deprivation>
Featured in radio article
- 2013 'Sleep' by John Maciel, KW Magazine, CKWR FM, Kitchener, Ontario, 1/23/13
Interviewed for live radio program
- 2013 'Non-24-hour sleep-wake disorder in the blind', Speaking Out for the Blind by Brian McCallen, American Council of the Blind radio, 5/15/13
<http://www.acbradio.org/node/30>
Interviewed for radio show
- 2013 'Frontiers: Chronotypes' by Linda Geddes, BBC Radio 4, 12/18/13
<http://www.bbc.co.uk/programmes/b03lrzjp>
Interviewed for radio documentary
- 2014 'Sleepy teenagers experiencing body clock changes could be helped by delayed school hours: experts', by Louise Milligan ABC 7.30 Show, Australia, 5/28/14
<http://www.abc.net.au/news/2014-05-28/sleepy-teenagers-experiencing-body-clock-changes/5484766>
Interviewed for TV article
- 2015 'Brainwaves: Light', by Pennie Latin, BBC Radio Scotland, 1/5/15
<http://www.bbc.co.uk/programmes/b04ws7k9>
Interviewed for radio documentary
- 2016 'The Power of Light', NASA 12/13/16
<https://youtu.be/HBtdbaSKexU>
Featured in light and space video article
- 2016 'School of the Future' by Jane Teeling, NOVA, PBS, 9/14/16
<http://www.pbs.org/wgbh/nova/body/school-of-the-future.html>
Advisor to TV documentary on light and sleep
- 2017 'Sleep Awareness Week' by 3AW Breakfast with Ross and John, Melbourne, Australia, 7/4/17
Interviewed for live radio program
- 2017 'Blind people and sleep' by Jonathan Mosen, Blind Side Podcast 46, 8/1/17
<http://dts.podtrac.com/redirect.mp3/feeds.soundcloud.com/stream/335811288-theblindsidepodcast-episode46.mp3>
<https://soundcloud.com/theblindsidepodcast>
Interviewed for podcast
- 2018 'Built for Health – Lighting' USGBC podcast series #5, 3/9/18
<https://www.usgbc.org/articles/usgbc-premieres-human-health-podcast-built-health>
<https://soundcloud.com/usgbc/built-for-health-light>
Interviewed for podcast series
- 2018 Circadian rhythms and light – World Sleep Day' ABC Perth radio, 3/16/18
Interviewed for live radio
- 2018 'The science of sleep and requirements of good rest' by James Hewitt, Hints Performance, September 2018

<http://www.hintsa.com/talking-with-steven-lockley-science-of-sleep/>

Interviewed for podcast
(Hintsa Performance)

- 2019 ‘Sleep: The most overlooked area of performance enhancement’ by Joshua Faga, Kickin’ It S04 E08, 6/4/19
<https://joshfaga.com/sleep-the-most-overlooked-and-undervalued-recovery-tool-for-high-performance-w-dr-steven-lockley/>
Interviewed for podcast

- 2020 ‘Fix Your Sleep—Understanding circadian rhythm, jetlag, & more’ by Dr Diva Nagula, From Doctor To Patient, 8/6/20
<https://podcasts.apple.com/gb/podcast/dr-steven-lockley-fix-your-sleep-understanding-circadian/id1490061447?i=1000487273817>
Featured in circadian rhythm and sleep podcast

- 2021 ‘Blindness and sleep’ by Joeita Gupta, The Pulse, AMI, 1/23/21
<https://podcasts.apple.com/ca/podcast/the-pulse-on-ami-audio/id1289703145>
Interviewed for podcast series

- 2021 ‘Sleep and circadian rhythms’ by Sam Kleckley, Live Life in Motion, 2/16/21
<https://podcasts.apple.com/us/podcast/live-life-in-motion/id1538684135?i=1000509517859>
Interviewed for podcast series

- 2021 ‘Sleep and circadian rhythms’ by Sam Kleckley, Live Life in Motion, 10/6/21
<https://podcasts.apple.com/us/podcast/live-life-in-motion/id1538684135?i=1000537712445>
Interviewed for podcast series

Articles in newspapers of magazines

- 1997 ‘“Darkness hormone” will give blind a good night’s sleep’ by J Illman, *The Observer*, 23 Feb
Research work featured in article
- 1998 ‘Does light have a dark side? Nighttime illumination might elevate cancer risk’ by Janet Raloff, *Science News*, 154, p248-250
http://www.sciencenews.org/sn_arc98/10_17_98/19981017fob.asp
Interviewed for health article
- 1998 ‘Blind people often sleep poorly; research shines light on therapy’ by Lynne Lamberg, *Journal of the American Medical Association*, 280, p1123-1126
Feature article about recent research findings
- 1999 ‘New day dawns for research on circadian rhythms’ by M. Kelly, *Lancet*, 353, p990
<http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2805%2970754-6/fulltext>
Feature article about recent research findings
- 2001 ‘Winding up my ageing body clock’ by John W. Goddard, *The Argus*
Research work featured in article

- 2003 'Restless nights, listless days' by Alison Abbott, *Nature*, 423 p896-898
<http://www.nature.com/nature/journal/v425/n6961/full/425896a.html>
Work and photograph featured in Nature News article
- 2003 'When light has you singing the blues' by William J. Cromie, *Harvard Gazette*, XCIX (2), p1,8 <https://news.harvard.edu/gazette/story/2003/09/when-light-has-you-singing-the-blues/>
Cover feature article about recent research findings
- 2004 'Overworked interns prone to medical errors' by William J. Cromie, *Harvard Gazette*, C (7), p1,4 <https://news.harvard.edu/gazette/story/2004/10/overworked-interns-prone-to-medical-errors/>
Cover feature article about recent research findings
- 2004 'Extended shifts for residents called risky for patients' by Courtney Humphries, *Harvard Focus*, November 12, 2004.
http://focus.hms.harvard.edu/2004/Nov12_2004/sleep_medicine.html
Feature article about recent research findings
- 2005 'You're getting sleepy; could that stop cancer?' by Judy Foreman, *Boston Globe*,
<http://www.nytimes.com/2005/10/05/health/05iht-snmel.html>
Interviewed for health article
- 2006 Carol Potera, *American Journal of Nursing*
Interviewed for health article
- 2006 'Melatonin effective in totally blind people' by Lynne Lambert, *Psychiatric News*, 41(17): p26.
Interviewed for health article
- 2006 'When the blues keep you awake' by William J. Cromie, *Harvard Gazette*, CI (15), p1,8 <https://news.harvard.edu/gazette/story/2006/02/when-the-blues-keep-you-awake/>
Cover feature article about recent research findings
- 2007 'Clockwise' by Melissa Hendricks, *John Hopkins Magazine*, 59(5)
<http://www.jhu.edu/~jhumag/1107web/clock.html>
Interviewed for general science article
- 2007 'Researchers discover second light-sensing system in human eye' by Alvin Powell, *Harvard Science*, December 13, 2007 <http://harvardscience.harvard.edu/medicine-health/articles/researchers-discover-second-light-sensing-system-human-eye>
Feature article about recent research findings
- 2007 'How blind people see sunrise and sunset' by Andy Coghlan, *New Scientist*, 196 (2635/2636), p9 <http://www.newscientist.com/article/mg19626354.100-blind-people-see-sunrise-and-sunset.html>
Feature article about recent research findings
- 2008 'Hungry for sleep' by Cassandra Willyard, *Nature Medicine*, 14(5), p477-480
<http://www.nature.com/nm/journal/v14/n5/full/nm0508-477.html>
Interviewed for health article
- 2008 'Good vibes need a body clock on song' by Bianca Nogrady, *Swinburne Magazine*,

- Issue 3, Sep, 2008 <http://www.swin.edu.au/magazine/3/77/good-vibes-need-a-body-clock-on-song/>
Interviewed for general science article
- 2009 'In search of sleep' by Nancy Rothstein, *Wealth Magazine*, Spring, p18-20
Interviewed for health article
- 2009 New York Academy of Sciences eBriefing 'Circadian Disruption and Cancer: Making the Connection' by Megan Stephan
<http://www.nyas.org/Publications/EBriefings/Detail.aspx?cid=96b356ff-72d7-4320-a2d3-e08ba4512cf3#>
Featured in meeting report and online lecture series
- 2009 'Napping may not be such a no-no' by Peter Wehrwein, *Harvard Health Letter*, 35(1)
Interviewed for health article (not named but work with firefighters mentioned)
- 2010 What's in a color? The unique human health effects of blue light' by David Holzman, *Environmental Health Perspective*, Focus News, 118(1); pA23-27
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2831986/>
Interviewed for health article
- 2010 'Perchance to heal' by Andrew Stephens, *The Age A2 Magazine*, January 30, 2010
<http://www.theage.com.au/news/entertainment/perchance-to-heal/2010/01/29/1264268075740.html>
Interviewed for health article
- 2010 'The night shift's got no rhythm' by Teresa Odle, *American Society of Radiologic Technologists Scanner Magazine*, Feb/Mar, 2010
Interviewed for health article
- 2010 'City lights illuminate a serious sleeping problem' by Andrew Stephens, *The Age A2 Magazine*, 3/27/10 <http://www.theage.com.au/national/city-lights-illuminate-a-serious-sleeping-problem-20100326-r37d.html>
Interviewed for health article
- 2010 'Vision cells help set the body's clock' by Gretchen Vogel, *Science Now*, 5/12/10
<http://news.sciencemag.org/sciencenow/2010/05/vision-cells-help-set-the-bodys-.html>
Feature article about recent research findings
- 2010 'An inner glow' by Emily Backus, *The Financial Times, House and Home*, 9/17/10
<http://www.ft.com/cms/s/2/89e3e744-c11e-11df-afe0-00144feab49a.html>
Interviewed for health article
- 2010 'Miners prepare for life after dark' by Adam Mann, *The Great Beyond*, 10/7/10
http://blogs.nature.com/news/thegreatbeyond/2010/10/miners_researchers_prepare_for.html
Interviewed for health article
- 2010 'Why you should go to bed early' by Laura Beil, *O Magazine*, 12/20/10
<http://www.oprah.com/health/The-Negative-Effects-of-Sleep-Loss>
Interviewed for health article
- 2011 'Vision science: Seeing without seeing' by Corie Lok, *Nature*, 469, p284-285, 1/19/11

- <http://www.nature.com/news/2011/110119/full/469284a.html>
Work and photograph featured in Nature News article
- 2011 'Why you should dim the lights at night', by Deborah Kotz, *Daily Dose, Boston Globe*, 1/20/11
http://www.boston.com/lifestyle/health/blog/dailydose/2011/01/why_you_should.html
Feature article about recent research findings
- 2011 'Kill the lights to keep melatonin flowing', by Nancy White, *Toronto Star*, 3/11/11
<http://www.healthzone.ca/health/mindmood/article/951924--kill-the-lights-to-keep-melatonin-flowing>
Interviewed for health article
- 2011 'Long shifts, lack of sleep fatigue health care workers: changing attitudes about rest and reasonable work schedules' by Kathleen Misovic, *Joint Commission Journal on Quality and Patient Safety*, 11, p9-11, March 2011
Interviewed for news article
- 2011 'BWH researcher sheds light on a dark topic', *BWH Bulletin*, 4/22/11
http://www.brighamandwomens.org/about_bwh/publicaffairs/news/publications/DisplayBulletin.aspx?articleid=5208
Feature article about documentary appearance
- 2011 'Blue alert: The dark side of night light' by David Holzman, *New Scientist*, 2811, 5/10/11
Interviewed for health article
- 2011 'In eyes, a clock calibrated by wavelengths of light' by Laura Beil, *New York Times*, 7/4/11
<http://www.nytimes.com/2011/07/05/health/05light.html>
Work featured in science article
- 2011 'NASA's Sleep Doc' by Franklin A. Holman, *Sleep Review*, Oct
http://www.sleepreviewmag.com/issues/articles/2011-10_01.asp
Interviewed for science article
- 2012 'The Brain' by Carl Zimmer, *Discover*, Jan, p12-13
Work featured in science article
- 2012 'Can't sleep? Your gadgets are keeping you up' by Kendra Srivastava, *Mobilemedia* 3/23/12
<http://www.mobiledia.com/news/134568.html>
Interviewed for science article
- 2012 'Blues Cues' by Elizabeth Dougherty, *Harvard Medicine*, Spring 2012
<http://hms.harvard.edu/content/blues-cues>
Featured in science article
- 2012 'Blue light has a dark side', *Harvard Health Letter*, May 2012
http://www.health.harvard.edu/newsletters/Harvard_Health_Letter/2012/May/blue-light-has-a-dark-side/
Featured in science article

- 2012 'Not Alert? Your Employees Will Get Hurt' by Marah Block, CBIA May 2012
<http://www5.cbiam.com/hr/article/not-alert-your-employees-will-get-hurt/>
Report on lecture
- 2012 'Instead of Coffee, Try Some Light' by Seth Porges, T. Rowe Price Connections, June 2012
<http://individual.troweprice.com/public/Retail/Planning-&-Research/Connections/Lighting/Instead-of-Coffee-Try-Some-Light>
Featured in science article
- 2012 'Digital devices interfering with good night's sleep' by Allison McGinley, WKMG Orlando, 6/6/12
<http://www.clickorlando.com/news/Digital-devices-interfering-with-good-night-s-sleep/-/1637132/14592120/-/15afh38/-/index.html>
Featured in news article
- 2012 'Where Have All the Stars Gone?' by Rebecca Jacobsen, PBS Newshour, 6/7/12
<https://www.pbs.org/newshour/science/where-did-all-the-stars-go>
Featured in news article
- 2012 'Artificial lighting poses health risks, American Medical Association asserts' by William Weir, *Hartford Courant*, 6/20/12
<http://www.courant.com/health/connecticut/hc-light-dangerous-ama-0621-20120620,0,257372.story>
Featured in news article
- 2012 'Better than sunshine: See life in an improved light' by Jeff Hecht, *New Scientist*, 6/27/12
Featured in science article
- 2012 'Sleep research in the blind may help us all' by Steven Lockley, *Huffington Post*, 7/2/12
http://www.huffingtonpost.com/steven-lockley-phd/circadian-rhythm-blind-people_b_1635828.html?utm_hp_ref=healthy-living
General interest science article
- 2012 'Light from electronics at night linked to sleep loss' by Monica Eng, *Chicago Tribune*, 7/8/12
http://articles.chicagotribune.com/2012-07-08/news/ct-met-night-light-sleep-20120708_1_blue-light-bright-light-steven-lockley
Featured in news article
- 2012 'Blind people often find it hard to align their sleep-wake cycle with 24-hour day' by Alyssa Botelho, *Washington Post*, 8/6/12
http://www.washingtonpost.com/national/health-science/blind-people-often-find-it-hard-to-align-their-sleep-wake-cycle-with-24-hour-day/2012/08/06/5578f090-bb0d-11e1-abd4-aec81b4466d_story.html?hpid=z13
Featured in science article
- 2012 'A battle plan for jet lag' by Stephanie Rosenbloom, *New York Times*, 8/15/12
<http://travel.nytimes.com/2012/08/19/travel/a-battle-plan-for-jet-lag.html>

Featured in science article

- 2012 'A new glow in the dark: Sleeping with blue light on' by Laura Johannes, *Wall Street Journal*, 8/28/12
<http://online.wsj.com/article/SB10000872396390444327204577615391893332580.html>

Featured in science article

- 2012 'End the nightmare of sleep loss' by Sarah Rainey, *The Telegraph*, 9/16/12
<http://www.telegraph.co.uk/news/features/9546327/End-the-nightmare-of-sleep-loss.html>

Featured in science article

- 2012 'Marketing Decoder: Healthy Hotel Rooms' by Andrea Petersen, *Wall Street Journal*, 9/19/12
<http://online.wsj.com/article/SB10000872396390444165804578006342166438614.html>

Featured in science article

- 2012 'How blue light and caffeine will help humans move to Mars' by Rebecca Boyle, *Popsci*, 10/11/12
www.popsci.com/science/article/2012-10/blue-light-and-caffeine-can-help-earth-evolved-humans-transition-mars-shift

Featured in science article

- 2012 'How to beat jetlag' by Nancy Trejos, *USA Today*, 11/7/12
<http://www.usatoday.com/story/travel/2012/11/07/thriving-on-the-road-how-to-fight-jet-lag/1690179/>

Featured in science article

- 2012 'The new brain drain (and who can blame them?)' by Sarah Rainey, *The Telegraph*, 11/10/12
<http://www.telegraph.co.uk/expat/9667069/The-new-brain-drain-and-who-can-blame-them.html>

Featured in general interest article

- 2012 'Malfunctioning body clock hinders sleep for many blind people' by Alyssa Botelho, *Boston Globe*, 11/12/12
<http://www.bostonglobe.com/lifestyle/health-wellness/2012/11/12/the-totally-blind-unable-perceive-light-are-often-afflicted-with-rare-sleep-disorder/ELcbAKFsLy1bFRrDaKDWM/story.html>

Featured in science article

- 2012 'Casting light on astronaut insomnia: ISS to get sleep-promoting lightbulbs' by Katie Worth, *Scientific American* 12/4/12
<http://www.scientificamerican.com/article.cfm?id=casting-light-on-astronaut-insomnia-iss-to-get-sleep-promoting-lightbulbs>

Featured in science article

- 2012 'Your body on...a long flight' by Laura Biel, *Women's Health*, 12/11/12
<http://www.womenshealthmag.com/health/flying-side-effects>

Source for health article

- 2013 'Morning glory' by Lisa Bendall, Best Health, *Jan/Feb*
<http://www.besthealthmag.ca/embrace-life/sleep/5-ways-to-improve-your-sleep>
Featured in health article
- 2013 'Fake mission to Mars leaves astronauts spaced out' by Ian Sample, The Guardian
1/7/13
<http://www.guardian.co.uk/science/2013/jan/07/fake-mission-mars-astronauts-spaced-out>
Featured in science article
- 2013 'Step into the Twilight Zone: Can Earthlings adjust to a longer day on Mars?' by Katie Worth, Scientific American, *1/29/13*
<http://www.scientificamerican.com/article.cfm?id=step-into-the-twilight-zone-can-earthlings-adjust-to-a-longer-day-on-mars>
Featured in science article and blog
- 2013 'Should medical residents be required to work shorter shifts?' Big Issues in Health Care, Wall Street Journal, *2/19/13*
<http://online.wsj.com/article/SB10001424127887324156204578273721688122486.html>
Featured in science article in and online debate
- 2013 'Chronobiology: Stepping out of time' by Michael Eisenstein, Nature 497, S10–S12
5/23/13
http://www.nature.com/nature/journal/v497/n7450_supp/full/497S10a.html?WT.ec_id=NATURE-20130523
Featured in science article
- 2013 'New medication may improve sleep in blind people' by Barbara Boughton, Medscape News Today, *6/18/13*
<http://www.medscape.com/viewarticle/806459>
Interviewed for science article
- 2013 'Drug helps blind patients sleep better' by Kristina Fiore, MedPage Today, *6/18/13*
<http://www.medpagetoday.com/MeetingCoverage/ENDO/39932>
Interviewed for science article
- 2013 'Is light pollution the easiest environmental problem to fix?', by Mindy Farabee, The Daily Beast, *7/17/13*
<http://www.thedailybeast.com/articles/2013/07/17/is-light-pollution-the-easiest-environmental-problem-to-fix.html>
Featured in science article
- 2013 'Sports beginning to see the energy-efficient light' by Ken Belson, New York Times, *10/9/13*
<http://www.nytimes.com/2013/10/09/business/energy-environment/sports-beginning-to-see-the-energy-efficient-light.html>
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7. Cappuccio FP, **Lockley SW**, Landrigan CP. Response to 'BMA warning over law limiting junior doctors' hours'. *The Guardian* 2008; <http://www.guardian.co.uk/society/2008/dec/30/junior-doctors-working-hours-bma>
8. Cappuccio FP, **Lockley SW**, Landrigan CP. Response to Comments re "Implementing a 48h EWTD-compliant rota for junior doctors in the UK does not compromise patients' safety: Assessor-blind pilot comparison". *Quarterly Journal of Medicine*, 2009; 102(5):363-4. PMID: 19318371.

Thesis

Lockley SW. Sleep, melatonin and other circadian rhythms in the blind [Ph.D. Thesis]. Guildford (Surrey): University of Surrey; 1997.

Abstracts, Poster Presentations and Exhibits Presented at Professional Meetings

(360 total [with 15]; 2019-2022 only listed; abstracts that are published as original reports or given as oral presentations are not included)

1. Brainard G, Clark T, St. Hilaire M, Rahman S, Hanifin J, Warfield B, Kemp D, Disoke F, Glodjo T, Jasser S, Ayers M, Panepinto L, Kanumilli S, Nelson N, Hasher D, Vadalía S, Balaicuis J, Byrne B, Pineda C, Gerner E, Maida J, Johnston S, Moomaw R, Barger L, Czeisler C, Lockley S. Testing solid state lighting countermeasures to improve circadian adaptation, sleep, and performance during high fidelity analog and flight studies for the International Space Station. Abstract. 2019 NASA Human Research Program Investigators' Workshop; 2019 Jan 22-25; Galveston, USA.
2. Phillips AJK, St. Hilaire MA, Sullivan JP, Barger LK, O'Brien CS, Rahman SA, Landrigan CP, **Lockley SW**, Klerman EB, Czeisler CA. Model-based predictions of neurobehavioral performance on resident physicians in a Randomized Order Safety Trial Evaluating Resident-physician Schedules (ROSTERS). Abstract. 33rd meeting of the Associated Professional Sleep Societies (APSS); 2019 June 8-12; San Antonio, USA.
3. Brainard G, Garcia D, Norwood K, Clark T, St. Hilaire M, Rahman S, Kemp J, Hanifin J, Warfield B, , Disoke F, Jasser S, Maida J, Johnston S, Moomaw R, Barger L, Czeisler C, **Lockley S**. Testing solid state lighting countermeasures to improve circadian adaptation, sleep, and performance during high fidelity analog and flight studies for the International Space Station (ISS). Abstract. 2020 NASA Human Research Program Investigators' Workshop; 2020 Jan 27-30; Galveston, USA.
4. Kent BA, Rahman SA, **Lockley SW**, St. Hilaire MA. Towards a real-time estimate of circadian phase during spaceflight. Abstract. 2020 NASA Human Research Program Investigators' Workshop; 2020 Jan 27-30; Galveston, USA.
5. Hilaire MA, Rahman SA, Flynn-Evans EE, Higgenbotham S, Witt-Enderby P, **Lockley SW**. Rhythms in urinary 6-sulfatoxymelatonin and the bone resorption marker amino-terminal crosslinked telopeptide of collagen I (NTx) in blind women. Abstract. Society for Research on Biological Rhythms (SRBR); 2020 May 30-June 3, Amelia Island, USA.
6. Rahman SA, Kent BA, St. Hilaire MA, Clark T, Hanifin JP, Barger LK, Czeisler CA, Brainard GC, **Lockley SW**. Lighting protocols for exploration – HERA campaign. Abstract. Society for Research on Biological Rhythms (SRBR); 2020 May 30-June 3, Amelia Island, USA.
7. Brainard G, Rahman S, Clark T, St. Hilaire M, Garcia D, Norwood K, Kemp J, Disoke F, Hanifin J, Warfield B, Maida J, Johnston S, Moomaw R, Barger L, Czeisler C, **Lockley S**. Testing solid state lighting countermeasures to improve circadian adaptation, sleep, and performance during high fidelity analog and flight studies for the International Space Station (ISS). Abstract. 2021 NASA Human Research Program Investigators' Workshop; 2021 Feb 1-4; Online.
8. Kent BA, Rahman SA, **Lockley SW**, St Hilaire MA. Towards a real-time estimate of circadian phase during spaceflight. Abstract. 2021 NASA Human Research Program Investigators' Workshop; 2021 Feb 1-4; Online.
9. Bulfin L, Endacott R, Kevat D, **Lockley S**, Ponnu M, Tiruvoipati R, Morphet J. Impact of AlertSafe medical scheduling on patient safety in the Intensive Care Unit. Abstract. European Society of Intensive Care Medicine LIVES 2021 Conference; 2021 Oct 3-6; Online.
10. Stone JE, Phillips AJK, Wiley JF, Chachos E, Hand AJ, Lu S, Carskadon MA, Klerman EB, **Lockley SW**, Bei B*, Rajaratnam SMW*. Changes in sleep-wake patterns, circadian timing,

and mood in Australian teens during the COVID-19 pandemic. Abstract. Sleep DownUnder 2021; 33rd Annual Scientific Meeting of the Australasian Sleep Association (ASA); 2021 Oct 10-13; Brisbane, Australia

11. Rahman SA, Kent BA, Grant LK, Clark T, Hanifin JP, Barger LK, Czeisler CA, Brainard GC, St. Hilaire MA, **Lockley SW**. Lighting protocols for exploration – HERA campaign. Abstract. 2022 NASA Human Research Program Investigators’ Workshop; 2022 Feb 7-10; Online.
12. St. Hilaire MA, Rahman SA, Grant LK, Gathungu RM, Struble J, Belenky M, Marur VR, Kristal BS, Sullivan JP, Quackenbush J, Duffy JF, Barger LK, Czeisler CA, **Lockley SW**. Development and testing of biomarkers to determine individual astronauts’ vulnerabilities to behavioral health disruptions. Abstract. 2022 NASA Human Research Program Investigators’ Workshop; 2022 Feb 7-10; Online.
13. Brainard G, Rahman S, Clark T, St. Hilaire M, Garcia D, Norwood K, Kemp J, Disoke F, Hanifin J, Warfield B, Maida J, Johnston S, Moomaw R, Barger L, Czeisler C, **Lockley S**. Testing solid state lighting countermeasures to improve circadian adaptation, sleep, and performance during high fidelity analog and flight studies for the International Space Station (ISS). Abstract. 2022 NASA Human Research Program Investigators’ Workshop; 2022 Feb 7-10; Online.
14. Kent BA, Rahman SA, **Lockley SW**, St Hilaire MA. Towards a real-time estimate of circadian phase during spaceflight. Abstract. 2022 NASA Human Research Program Investigators’ Workshop; 2022 Feb 7-10; Online.
15. Ivkovic V, Thoolen S, White BM, Zhang Q, Rahman SA, **Lockley SW**, Strangman GE. Operational performance measures: Effects of isolation and confinement, altered lighting, habitat volume, and enhanced nutrition on Robot-R in HERA. Abstract. 2022 NASA Human Research Program Investigators’ Workshop; 2022 Feb 7-10; Online.

Tab F

ANDREW PARKINSON, Ph.D.

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PERSONAL DATA

Born November 30th, 1954 in Bristol, England.
 Citizenship American (naturalized in 1996)
 Family Status Married with two sons and a daughter

EMPLOYMENT

2012 – present Chief Executive Officer, XPD Consulting, Shawnee, Kansas
 2010 – 2011 Chief Scientific Officer, XenoTech, LLC, Lenexa, Kansas
 2006 – 2010 Chief Executive Officer and Chief Scientific Officer, XenoTech, LLC, Lenexa, Kansas
 1999 – present Adjunct Professor of Pharmacology and Toxicology, Kansas University Medical Center
 1994 – 2006 President and CEO (and founder), XenoTech LLC, Lenexa, Kansas
 1990 – 1999 Professor of Pharmacology and Toxicology, Kansas University Medical Center
 1989 – 1999 Associate Director of the Center for Environmental & Occupational Health, KUMC
 1987 – 1990 Associate Professor of Pharmacology and Toxicology, KUMC
 1983 – 1987 Assistant Professor of Pharmacology and Toxicology, KUMC

EDUCATION

1981 – 1983 Postdoctoral training: Roche Institute of Molecular Biology, Hoffmann-La Roche, Nutley, NJ. Advisors: Dr. A.H. Conney and W. Levin
 1977 – 1981 Graduate (Ph.D.) degree: Department of Chemistry, University of Guelph, Ontario, Canada. Ph.D. in Biological Chemistry. Advisor: Professor Stephen H. Safe
 1973 – 1977 Undergraduate (B.S.) degree: Department of Biochemistry, University of Surrey, England. B.Sc. with First Class Honors (*Magna Cum Laude*) in Medical Biochemistry

AWARDS

1981 D.G. Ingram Sigma Xi award for outstanding graduate research
 1986 Research Career Development Award, National Institutes of Health
 1987 Faculty Research Development Award, University of Kansas Medical Center
 1990 Walter J. Johnson Award for the Best Paper published in *Archives of Biochemistry and Biophysics* between 1987 and 1990
 1991 Award for Best Paper published in *Drug Metabolism and Disposition* in 1990
 1996 Technology of the Year Award (Bioscience Division), Silicon Prairie Technology Association.
 1999 Ernst & Young Entrepreneur of the Year; Finalist, Kansas and Western Missouri
 2000 Association of Caring Entrepreneurs; Finalist in the *Success Against All Odds* award
 2003 Recipient of Technology Award from the University of Kansas
 2005 Finalist for Kansas Exporter of the Year, Kansas Department of Commerce
 2006 Finalist for Kansas Exporter of the Year, Kansas Department of Commerce
 2006 DMPK Award from JSSX for the Most Frequently Downloaded Original Article in 2002 (published in *Drug Metab. Pharmacokinetics* **17**: 482-487, 2002)
 2012 John Doull Award from the Central States Chapter of the Society of Toxicology
 2014 The XenoTech Scientific Excellence Award (inaugural recipient)

APPOINTMENTS

1990 – 2000 Scientific Consulting Committee (Drug Safety), Schering Plough Corporation
 1993 – 1995 Scientific Consulting Committee, Takeda-Abbott Pharmaceutical Corporation
 1995 – 1998 Board of Directors, Kansas University Medical Center-Research Institute
 1998 – 1999 Special government employee (consultant to the Food & Drug Administration)
 1999 – 2000 Corporate Advisory Committee, National Disease Research Interchange (NDRI)
 2003 – 2006 Scientific Consulting Committee (Preclinical Drug Development), Abbott Laboratories
 2004 – 2006 Scientific Advisory Board, MultiCell Technologies
 2009 – 2013 Member of the Board of Directors of Yecuris
 2017 – present Member of the Scientific Advisory Board of Yecuris
 2020 – present Member of the Scientific Advisory Board of Attentive Science
 2021 – present Member of the Board of Directors, Attentive Science

MEMBERSHIP IN PROFESSIONAL SOCIETIES

American Society for Pharmacology and Experimental Therapeutics (ASPET)
 International Society for the Study of Xenobiotics (ISSX)
 Society of Toxicology (SOT)

APPOINTMENTS TO SCIENTIFIC SOCIETAL COMMITTEES

1990 – 1992 Society of Toxicology (SOT): Education Committee
 1992 – 1994 ASPET: Drug Metabolism Division
 1994 – 1998 ISSX: Councilor
 1995 – 1996 ISSX: Meeting organizer and chairman
 1999 – 2000 ISSX: Scientific Advisory Board for the Year 2000 annual meeting.
 2002 – 2005 Microsomes & Drug Oxidations (MDO): International Organizing Committee
 2002 – 2009 ISSX: Exhibitors Committee
 2014 – 2016 Treasurer, International Society of Xenobiotics (ISSX)
 2017 – 2018 ISSX: Head of the Finance Committee
 2019 – present ISSX: Continuing Education Committee

APPOINTMENTS TO EDITORIAL BOARDS

1987 – 1991 Environmental Toxin Reviews
 1989 – 2004 Archives of Biochemistry and Biophysics
 1991 – 2005 Journal of Biochemical and Molecular Toxicology
 1992 – 1994 Xenobiotica
 1993 – 2005 Drug Metabolism and Disposition

PATENTS

Patent No.: US 5,478,723. A method and apparatus for determining the role of cytochrome P450 and related enzymes in the metabolism of drugs and other chemicals. Issued 26 December, 1995.

Patent No.: US 9,085,793. *Ex vivo* method to identify drug metabolites with drug interaction potential. Issued 21 July, 2015.

Patent No. US. 10,517,860. Combination of pimavanserin and cytochrome P450 modulators. Issued 31 December, 2019.

GRANT REVIEW & NIH STUDY SECTIONS

1987 Specialty reviewer, United States Air Force
 1988 Specialty reviewer, New York Sea Grant Institute
 1989 Specialty reviewer, Toxicology Study Section of NIEHS
 1991 Specialty reviewer, Veterans Administration Hospital, University of Kentucky
 1991 Specialty reviewer, Site Visit Team Member for NIGMS
 1992 Specialty reviewer, Site Visit Team Member for NIGMS
 1992 Specialty reviewer, Veterans Administration Medical Center, Livermore, CA
 1993 Specialty reviewer for NIGMS, Site Visit Team Member
 94 – 98 Study section member, NIEHS centers, programs and training grants

TRAINEES: Postdoctoral fellows, research assistant professors and visiting scientists

Postdoctoral fellows	Date	Doctoral (Ph.D.) students	Date
Michael Halvorson, Ph.D.	1987 – 1989	Michael P. Arlotto	1984 – 1988
Bingfang Yan, Ph.D.	1989 – 1992	Andrew J. Sonderfan	1984 – 1988
Uma Sanzgiri, Ph.D.	1993 – 1995	David R. Dutton	1984 – 1988
Ajay Madan, Ph.D.	1994 – 1997	Delmont C. Eberhart	1988 – 1991
Edward LeCluyse, Ph.D.	1995 – 1996	Brian Gemzik	1988 – 1992
Kyle Kramer, Ph.D.	1995 – 1996	Peter Bullock	1989 – 1995
Research assistant professor		Robin Pearce	1992 – 1996
Bingfang Yan, DVM, Ph.D.	1994 – 1995	Christin (Coulter) McIntyre	1992 – 1997
Maciej Czerwinski, Ph.D.	1998 – 1999	Bingfang Yan	1992 – 1995
Visiting scientists		Alison Draper	1994 – 1996
Larry Robertson, Ph.D.,	1993	Peter Opdam	1996 – 2003
Masters (MS) students		Brian W. Ogilvie	2007 – 2015
Robin Pearce		Faraz Kazmi	2011 – 2015
Neda Leonard			
Aida Howell			
Ning Deng			

PUBLICATIONS. PART A: PEER-REVIEWED ARTICLES

1. Parkinson A and Safe S. The detection of enzyme induction by rat liver microsomes prepared by isoelectric precipitation. *J. Pharmac. Pharmacol.* **31**, 444-447, 1979.
2. Parkinson A, Cockerline R and Safe S. Induction of both 3-methylcholanthrene- and phenobarbitone-type microsomal enzyme activity by a single polychlorinated biphenyl isomer. *Biochem. Pharmacol.* **29**, 259-262, 1980.
3. Robertson LW, Parkinson A and Safe S. Induction of both cytochromes P-450 and P-448 by 2,3',4,4',5-pentabromobiphenyl, a component of fireMaster. *Biochem. Biophys. Res. Commun.* **92**, 175-182, 1980.
4. Parkinson A, Cockerline R and Safe S. Polychlorinated biphenyl isomers and congeners as inducers of both 3-methylcholanthrene- and phenobarbitone-type microsomal enzyme activity. *Chem.-Biol. Interact.* **29**, 277-289, 1980.
5. Parkinson A, Robertson LW, Safe L and Safe S. Polychlorinated biphenyls as inducers of hepatic microsomal enzymes: Structure-activity rules. *Chem.-Biol. Interact.* **30**, 271-285, 1980.
6. Parkinson A, Copp L and Safe S. The utility of the microsomal 4-chlorobiphenyl hydroxylase enzyme assay in distinguishing between phenobarbitone- and 3-methylcholanthrene-induced microsomal monooxygenases. *Anal. Biochem.* **105**, 65-73, 1980.
7. Parkinson A, Robertson LW and Safe S. Reconstituted human breast milk PCBs as potent inducers of aryl hydrocarbon hydroxylase (AHH). *Biochem. Biophys. Res. Commun.* **96**, 882-889, 1980.
8. Parkinson A, Robertson LW and Safe S. Hepatic microsomal enzyme induction by 2,2',3,3',4,4'- and 2,2',3',4,4',5-hexachlorobiphenyl. *Life Sciences* **27**, 2333-2337, 1980.
9. Parkinson A, Robertson LW, Safe L and Safe S. Polychlorinated biphenyls as inducers of hepatic microsomal enzymes: Effects of di-ortho-substitution. *Chem.-Biol. Interact.* **35**, 1-12, 1981.
10. Robertson LW, Parkinson A, Bandiera S and Safe S. Potent induction of rat liver microsomal, drug metabolizing enzymes by 2,3,3',4,4',5-hexabromobiphenyl, a component of fireMaster. *Chem.-Biol. Interact.* **25**, 13-24, 1981.
11. Robertson LW, Parkinson A, and Safe S. Induction of drug-metabolizing enzymes by fractionated commercial polybrominated biphenyls (PBBs). *Toxicol. Appl. Pharmacol.* **57**, 257-262, 1981.
12. Robertson LW, Parkinson A, Chittim B, Bandiera S, Sawyer TW and Safe S. Aryl hydrocarbon hydroxylase (AHH) induction of polybrominated biphenyls (PBBs): Enhancement by photolysis. *Toxicology* **22**, 103-114, 1981.
13. Campbell MA, Bandiera S, Robertson LW, Parkinson A and Safe S. Octachloronaphthalene induction of hepatic microsomal aryl hydrocarbon hydroxylase activity in the immature male rat. *Toxicology* **22**, 123-132, 1981.
14. Parkinson A and Safe S. The cytochrome P-450-mediated metabolism of biphenyl and 4-halobiphenyls. *Biochem. Pharmacol.* **31**, 1849-1856, 1982.
15. Parkinson A, Robertson LW, Uhlig L, Campbell MA and Safe S. 2,3,4,4',5-Pentachlorobiphenyl: Differential effects on the C57BL/6J and DBA/2J inbred mice. *Biochem. Pharmacol.* **31**, 2830-2833, 1982.
16. Parkinson A, Robertson LW and Safe S. The binding of metyrapone to dithionite-reduced cytochrome P-450 from rats treated with xenobiotics. *Biochem. Pharmacol.* **31**, 3489-3494, 1982.
17. Robertson LW, Parkinson A, Campbell MA and Safe S. Polybrominated biphenyls (PBBs) as aryl hydrocarbon hydroxylase inducers: Structure-activity correlations. *Chem.-Biol. Interact.* **42**, 53-66, 1982.

18. Parkinson A, Lasker J, Kramer MJ, Huang M-T, Thomas PE, Ryan DE, Reik LM, Norman RL, Levin W and Conney AH. Effects of three recombinant human leukocyte interferons on drug metabolism in mice. *Drug Metab. Dispos.* **10**, 579-585, 1982.
19. Parkinson A, Safe SH, Robertson LW, Thomas PE, Ryan DE, Reik LM and Levin W. Immunochemical quantitation of cytochrome P-450 isozymes and epoxide hydrolase in liver microsomes from polychlorinated biphenyl-treated rats: A study of structure-activity relationships. *J. Biol. Chem.* **258**, 5967-5976, 1983.
20. Campbell MA, Bandiera S, Robertson L, Parkinson A and Safe S. Hepta-, hexa-, tetra- and dichloro-naphthalene congeners as inducers of hepatic microsomal drug-metabolizing enzymes. *Toxicology* **26**, 193-205, 1983.
21. Parkinson A, Robertson L and Safe S. Induction of rat liver hepatic microsomal cytochrome P-450 by 2,3',4,4',5,5'-hexachlorobiphenyl. *Biochem. Pharmacol.* **32**, 2269-2279, 1983.
22. Parkinson A, Thomas PE, Ryan DE, Reik LM, Safe SH, Robertson LW and Levin W. Differential time course of induction of rat liver microsomal cytochrome P-450 isozymes and epoxide hydrolase by Aroclor 1254. *Arch. Biochem. Biophys.* **225**, 203-215, 1983.
23. Parkinson A, Thomas PE, Ryan DE and Levin W. The *in vivo* turnover of rat liver microsomal epoxide hydrolase and both the apoprotein and heme moieties of specific cytochrome P-450 isozymes. *Arch. Biochem. Biophys.* **225**, 216-236, 1983.
24. Robertson LW, Thompson K and Parkinson A. Synthesis, characterization and biologic effects of polybrominated naphthalenes. *Arch. Toxicology* **55**, 127-131, 1984.
25. Robertson LW, Parkinson A, Bandiera S, Lambert I, Merrill J and Safe S. PCBs and PBBs: Biologic and toxic effects on C57BL/6J and DBA/2J inbred mice. *Toxicology* **31**, 191-206, 1984.
26. Robertson L, Safe S, Parkinson A, Pellizzari E, Pochini C and Mullin M. Synthesis and identification of highly toxic polybrominated biphenyls in the fire retardant, fireMaster BP-6. *J. Agric. Food Chem.* **32**, 1107-1111, 1984.
27. Gorski J, Arlotto M, Klaassen CD and Parkinson A. Age- and sex-dependent induction of liver microsomal benzo[a]pyrene hydroxylase activity in rats treated with pregnenolone-16 α -carbonitrile (PCN). *Carcinogenesis*, **6**, 617-624, 1985.
28. Rozman K, Hazelton GA, Klaassen CD, Arlotto MP and Parkinson A. Effect of thyroid hormones on liver microsomal enzyme induction in rats exposed to 2,3,7,8-tetrachlorodibenzo-p-dioxin. *Toxicology*, **37**, 51-63, 1985.
29. Rozman K, Gorski J, Rozman P and Parkinson A. Reduced serum thyroid hormone levels in hexachlorobenzene-induced porphyria. *Toxicology*, **30**, 71-78, 1986.
30. Parkinson A, Ryan DE, Thomas PE, Jerina DM, Sayer JM, van Bladeren P, Haniu M, Shively JE and Levin W. Chemical modification and inactivation of rat liver microsomal cytochrome P-450c by 2-bromo-4'-nitroacetophenone. *J. Biol. Chem.* **261**, 11478-11486, 1986.
31. Parkinson A, Ryan DE, Thomas PE, Jerina DM, Sayer JM, van Bladeren P, Haniu M, Shively JE and Levin W. Mechanism of inactivation of rat liver microsomal cytochrome P-450c by 2-bromo-4'-nitroacetophenone. *J. Biol. Chem.* **261**, 11487-11495, 1986.
32. Arlotto MP, Sonderfan AJ, McKinney MM and Parkinson A. Digitoxin metabolism by liver microsomal cytochrome P-450 and UDP-glucuronosyltransferase and its role in the protection of rats from digitoxin toxicity by pregnenolone-16 α -carbonitrile. *Arch. Biochem. Biophys.* **251**, 188-197, 1986.
33. McKinney MM and Parkinson A. A simple, non-chromatographic procedure to purify immunoglobulins from serum and ascites fluid. *J. Immunol. Methods.* **96**, 271-278, 1987.

34. Sonderfan AJ, Arlotto MP, Dutton DR and Parkinson A. Regulation of testosterone hydroxylation by rat liver microsomal cytochrome P-450. *Arch. Biochem. Biophys.* **255**, 27-41, 1987.
35. Dutton DR, McMillen SK, Sonderfan AJ, Thomas PE and Parkinson A. Studies on the rate-determining factor in testosterone hydroxylation by rat liver microsomal cytochrome P-450. Evidence against cytochrome P-450 isozyme: isozyme interactions. *Arch. Biochem. Biophys.* **255**, 316-328, 1987.
36. Rozman K, Gorski J, Dutton D and Parkinson A. Effects of vitamin A and/or thyroidectomy on liver microsomal enzymes and their induction in 2,3,7,8-tetrachlorodibenzo-p-dioxin treated rats. *Toxicology*. **46**, 107-117, 1987.
37. Arlotto MP, Sonderfan AJ, Klaassen CD and Parkinson A. Studies on the pregnenolone-16 α -carbonitrile-inducible form of rat liver microsomal cytochrome P-450 and UDP-glucuronosyltransferase. *Biochem. Pharmacol.* **36**, 3859-3866, 1987.
38. Astroff B, Zacharewski T, Safe S, Arlotto MP, Parkinson A, Thomas P and Levin W. 6-Methyl-1,3,8-trichlorodibenzofuran (MCDF) as a TCDD antagonist: Inhibition of the induction of rat liver microsomal cytochrome P-450 isozymes and related monooxygenases. *Mol. Pharmacol.* **33**, 231-236, 1988.
39. Dutton DR, McMillen SK and Parkinson A. Purification of rat liver microsomal cytochrome P-450b without the use of non-ionic detergent. *J. Biochem. Toxicol.* **3**, 131-145, 1988.
40. Sonderfan AJ and Parkinson A. Inhibition of steroid 5 α -reductase and its effects on testosterone hydroxylation by rat liver microsomal cytochrome P-450. *Arch. Biochem. Biophys.* **265**, 208-218, 1988.
41. Halvorson MR, Safe SH, Parkinson A and Phillips TD. Aflatoxin B₁ hydroxylation by the pregnenolone-16 α -carbonitrile-inducible form of rat liver microsomal cytochrome P-450. *Carcinogenesis*, **9**, 2103-2108, 1988.
42. Parkinson A, Thomas PE, Ryan DE, Levin W, Fujita T and Safe S. Induction of rat liver microsomal cytochrome P-450 and epoxide hydrolase by a series of 4'-substituted-2,3,4,5-tetrachlorobiphenyls. *Toxicology*, **53**, 289-300, 1988.
43. Dutton DR, Reed G and Parkinson A. Redox cycling of resorufin catalyzed by rat liver microsomal NADPH-cytochrome P-450 reductase. *Arch. Biochem. Biophys.* **268**, 605-616, 1989.
44. Dutton DR and Parkinson A. Reduction of 7-alkoxyresorufins by NADPH-cytochrome P-450 reductase and its differential effects on their O-dealkylation by rat liver microsomal cytochrome P-450. *Arch. Biochem. Biophys.* **268**, 617-629, 1989.
45. Arlotto MP, Greenway D and Parkinson A. Purification of two isozymes of rat liver microsomal cytochrome P-450 with testosterone 7 α -hydroxylase activity. *Arch. Biochem. Biophys.* **270**, 441-457, 1989.
46. Arlotto MP and Parkinson A. Identification of cytochrome P-450a (P-450IIA1) as the principal testosterone 7 α -hydroxylase in rat liver microsomes and its regulation by thyroid hormones. *Arch. Biochem. Biophys.* **270**, 458-471, 1989.
47. Sonderfan AJ, Arlotto MP and Parkinson A. Identification of the cytochrome P-450 isozymes responsible for the hydroxylation of testosterone in rat lung, kidney and testis. Evidence that cytochrome P-450a (P-450IIA1) is the physiologically important testosterone 7 α -hydroxylase in rat testis. *Endocrinology*, **125**, 857-886, 1989.
48. Halvorson MR, Greenway D, Eberhart D, Fitzgerald K and Parkinson A. Reconstitution of testosterone oxidation by purified rat cytochrome P-450p (IIIA1). *Arch. Biochem. Biophys.* **277**, 166-180, 1990.

49. Gemzik B, Halvorson MR and Parkinson A. Pronounced and differential effects of ionic strength and pH on the catalytic activity of membrane-bound and purified forms of rat liver microsomal cytochrome P-450. *J. Steroid Biochem.* **35**, 429-440, 1990.
50. Crespi CL, Penman BW, Leakey JAE, Arlotto MP, Stark A, Parkinson A, Turner T, Steimel DT, Rudo K, Davies RL and Langenbach R. Human cytochrome P450IIA3: cDNA sequence, role of the enzyme in the metabolic activation of promutagens, comparison to nitrosamine activation by human cytochrome P450IIE1. *Carcinogenesis* **11**, 1293-1300, 1990.
51. Korzekwa KR, Trager WF, Nagata K, Parkinson A and Gillette JR. Isotope effect studies on the mechanism of the cytochrome P-450IIA1-catalyzed formation of Δ^6 -testosterone from testosterone. *Drug Metab. Dispos.* **18**, 974-979, 1990.
52. Bullock PL, Gemzik B, Johnson DC, Thomas PE and Parkinson A. Evidence from dwarf rats that growth hormone may not regulate the sexual differentiation of liver cytochrome P-450 enzymes and steroid 5 α -reductase. *Proc. Natl. Acad. Sci. USA.* **88**, 5227-5231, 1991.
53. Ramsdell HS, Parkinson A, Eddy AC, and Eaton DL. Bioactivation of aflatoxin B₁ by human liver microsomes: role of cytochrome P450 IIIA enzymes. *Toxicol. Appl. Pharmacol.* **108**, 436-447, 1991.
54. Thibeault DW, Downing G, Reddy N, Sonderfan AJ and Parkinson A. Oxygen-induced lung damage in newborn rats, potentiation by 3-methylcholanthrene, a P-450 inducer, and lack of protection by cimetidine, a P-450 inhibitor. *J. Pharmacol. Exp. Ther.* **259**, 444-451, 1991.
55. Eberhart DC and Parkinson A. Cytochrome P450 IIIA1 (P450p) requires cytochrome b₅ and phospholipid with unsaturated fatty acids. *Arch. Biochem. Biophys.* **291**, 231-240, 1991.
56. Eberhart DC, Gemzik B, Halvorson MR and Parkinson A. Species differences in the toxicity and cytochrome P450 IIIA-dependent metabolism of digitoxin. *Mol. Pharmacol.* **40**, 859-867, 1991.
57. Seng JE, Leakey JE, Arlotto MP, Parkinson A and Gandy J. Cellular localization of cytochrome P450 IIA1 in testes of mature male Sprague-Dawley rats. *Biol. Reproduction* **45**, 876-882, 1991.
58. Eberhart DC, Fitzgerald K and Parkinson A. Evidence for the involvement of a distinct form of cytochrome P-450 3A in the oxidation of digitoxin by rat liver microsomes. *J. Biochem. Toxicol.* **7**, 53-64, 1992.
59. Gemzik B, Greenway D, Nevins C and Parkinson A. Regulation of two electrophoretically distinct proteins recognized by antibody against rat liver microsomal cytochrome 3A1. *J. Biochem. Toxicol.* **7**, 43-52, 1992.
60. Parkinson A, Clement RP, Casciano CN and Cayen MN. Evaluation of loratadine as an inducer of liver microsomal cytochrome P450 in rats and mice. *Biochem. Pharmacol.* **43**, 2169-2180, 1992.
61. Gemzik B, Green J and Parkinson A. Hydroxylation of 5 α -androstane-3 β ,17 β -diol by rat prostate microsomes: Effects of antibodies and chemical inhibitors of cytochrome P450 enzymes. *Arch. Biochem. Biophys.* **296**, 355-365, 1992.
62. Gemzik B and Parkinson A. Hydroxylation of 5 α -androstane-3 β ,17 β -diol by rat prostate microsomes: Potent inhibition by imidazole-type antimycotic drugs and lack of inhibition by steroid 5 α -reductase inhibitors. *Arch. Biochem. Biophys.* **296**, 366-373, 1992.
63. Gemzik B, Jacobs S, Jennings S, Veltman J and Parkinson A. Species differences in 5 α -androstane-3 β ,17 β -diol hydroxylation by rat, monkey and human prostate microsomes. *Arch. Biochem. Biophys.* **296**, 374-383, 1992.
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PUBLICATIONS PART B: REVIEWS, BOOK CHAPTERS AND EDITORIALS

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INVITED LECTURES

Year	Institution or meeting	Title of presentation
1984	Texas A & M, College Station, TX	<i>Turnover of the apoprotein and the heme moiety of cytochrome P450.</i>
1986	Rutgers University, New Brunswick, NJ	<i>Studies on the metabolism and toxicity of digitoxin</i>
1987	USA MRICD, Aberdeen Proving Grounds, MD	<i>Purification and characterization of rat liver microsomal carboxylesterases</i>
1988	National Center for Toxicological Research, Jefferson, AK	<i>Testosterone oxidation by rat liver microsomal cytochrome P450</i>
1988	University of Arkansas, Little Rock, AK	<i>Studies on the metabolism and toxicity of digitoxin</i>
1989	University of Kentucky, Lexington, KY	<i>Regulation of testosterone oxidation by cytochrome P450</i>
1989	Annual Meeting of the American Chemical Society	<i>Purification and characterization of rat liver microsomal esterases</i>
1990	Eli Lilly & Company, Greenfield, IN	<i>Species differences in cytochrome P450</i>
1990	Marion Laboratories, Kansas City, MO	<i>Induction of rat liver microsomal cytochrome P450</i>
1990	Rutgers University, Piscataway, NJ	<i>Studies on the function and regulation of rat liver cytochrome P450p (IIIA1)</i>
1990	ISSX, San Diego, CA	<i>Antibodies as reagents and probes for the study of P450 enzymes</i>
1991	Schering Plough, Kenilworth, NJ	<i>In vitro and in vivo methods to evaluate the induction of liver microsomal cytochrome P450</i>
1991	Merck Sharp & Dohme (Gastroenterology Meeting) Marina del Rey, CA	<i>Induction of cytochrome P450 by omeprazole and its clinical and toxicological significance</i>
1991	Alcon Laboratories, Fort Worth, TX	<i>In vitro and in vivo methods to evaluate the induction of liver microsomal cytochrome P450</i>
1991	Astra and Merck Sharp & Dohme (Hanbury conference), London, England	<i>Invited participant in a three-day workshop on anti-secretory/anti-ulcer drugs</i>
1991	Procter & Gamble Company, Cincinnati, OH	<i>Species differences in the function and regulation of cytochrome P450</i>
1991	ISSX, Amsterdam, Netherlands. A debate with Drs. J. Caldwell, D.V. Parke and P. Maurel	<i>Induction of P450 IA is an indicator of carcinogenicity or other severe toxic effects</i>
1991	Alcon Laboratories, Fort Worth, TX	<i>Induction of cytochrome P450 in Cynomolgus monkeys</i>
1991	Society of Toxicology, Ohio Valley Chapter, University Kentucky, Lexington, KY	<i>Is cytochrome P450 induction hazardous to your health?</i>

Year	Institution or meeting	Title of presentation
1991	Schering Plough, Kenilworth, NJ	<i>Human and monkey P450 enzymes and inter-individual differences in drug metabolism</i>
1991	Procter & Gamble, Cincinnati, OH	<i>Induction of human liver P450 enzymes in vitro</i>
1991	Annual meeting of the Missouri-Kansas Reproductive Endocrinology Society	<i>Species differences in androgen metabolism in the prostate</i>
1992		
1992 (Jan)	Wyeth-Ayerst Research, Philadelphia, PA	<i>Cytochrome P450: An overview</i>
1992 (Feb)	Sigma Xi Seminar Series, University of Kansas Medical Center, Kansas City, KS	<i>Cytochrome P450: A point of interaction with environmental and occupational chemicals</i>
1992 (Mar)	University of Texas, Southwestern Medical School, Dallas, TX	<i>Species differences in the inactivation of androgens in the prostate</i>
1992 (Mar)	Norwich Eaton Pharmaceuticals, Norwich, NY	<i>Species differences in the toxicity and cytochrome P450 3A-dependent metabolism of digitoxin</i>
1992 (Mar)	Department of Biochemistry, University of Kansas Medical Center, Kansas City, KS	<i>Cytochrome P450: A molecular biologist's dream, a toxicologist's nightmare</i>
1992 (Apr)	Annual meeting of the Central States Chapter of the Society of Toxicology, Kansas City, KS	<i>Species differences in cytochrome P450</i>
1992 (May)	Pfizer Inc., Groton, CT	<i>Cytochrome P450: Problems and solutions in drug development</i>
1992 (May)	Abbott Laboratories, Abbott Park, IL	<i>Cytochrome P450: Problems and solutions in drug development</i>
1992 (Jul)	Microsomes & Drug Oxidations (Ninth International Symposium), Jerusalem, Israel	<i>Prostate cytochrome P450</i>
1992 (Jul)	Annual meeting of the Society for the Study of Reproduction, North Carolina State University, Raleigh, NC	<i>Workshop on Recombinant Proteins: Expression, Analysis and Characterization</i>
1992 (Jul)	Wyeth-Ayerst Research, Philadelphia, PA	<i>Effects of cytochrome P450 inducers on the hepatotoxicity of tolrestat in rats</i>
1992 (Nov)	Indiana University, Indianapolis, IN	<i>Prediction of human drug metabolism patterns based on in vitro approaches</i>
1993		
1993 (Jan)	National Academy of Sciences: Institute of Medicine, Washington, DC	<i>Speaker and panel member at a workshop on: Enzymes of drug metabolism: Importance to drug safety and efficacy</i>
1993 (Apr)	Midwest Research Institute, Kansas City, MO	<i>New opportunities in pre-clinical drug development and safety evaluation</i>
1993 (May)	North Jersey Drug Metabolism Discussion Group. Nutley, NJ	<i>Enzyme induction: The Good, the Bad and the Ugly</i>

Year	Institution or meeting	Title of presentation
1993 (May)	Workshop on Acid-Related Disorders: Clinical Science and Implications for Management. Boston, MA	<i>Implications and clinical relevance of interactions with drugs and carcinogens</i>
1993 (June)	Environmental Protection Agency (EPA), Research Triangle Park, NC	<i>In vitro approaches to study human drug metabolism</i>
1993 (Sept)	Purdue University, West Lafayette IN	<i>Human drug metabolism: some apparent discrepancies between in vitro and in vivo reaction phenotyping. Canceled due to illness</i>
1993 (Oct)	ISSX Continuing Education Course on the Structure, Function and Regulation of selected Phase I & II Enzymes. Tucson, AZ.	<i>Hydrolytic enzymes and oxidoreductases</i>
1993 (Oct)	ISSX Organizer of a session on Species Differences in Cytochrome P450 Function and structure. Tucson, AZ	<i>Species differences in cytochrome P450 function</i>
1993 (Dec)	Department of Medicinal Chemistry, University of Kansas, Lawrence, KS	<i>In vitro approaches to study human drug metabolism</i>
1994		
1994 (Apr)	Pfizer Inc., Groton, CT	<i>Why, how and when should drugs be evaluated as inducers of cytochrome P450 and UDP-glucuronosyltransferase</i>
1994 (May)	Kansas City Discussion Group of Pharmaceutical and Allied Sciences, Kansas City, MO	<i>Cytochrome P450 induction and metabolism in drug development</i>
1994 (Jul)	Microsomes and Drug Oxidations (10th International Symposium), Toronto, Canada	<i>Purification and cloning of rat carboxylesterases</i>
1994 (Oct)	Annual meeting of Amersham, FL	<i>Tools and techniques for P450 analysis</i>
1994 (Oct)	ISSX, Raleigh-Durham, NC	<i>In vitro approaches to studying human P450 enzymes</i>
1994 (Nov)	American Industrial Hygiene Association, Mid-America Local Section, Lee's Summit, MO	<i>Inter-individual differences in cytochrome P450: Implications for risk assessment</i>
1994 (Nov)	Procter & Gamble, Cincinnati, OH	<i>Induction of cytochrome P450 in primary cultures of rat hepatocytes</i>
1995		
1995 (Jan)	Research Institute of Fragrance Manufacturers, Naples, FL	<i>Coumarin metabolism</i>
1995 (Feb)	Allergan, Irvine, CA	<i>The role of cytochrome P450 induction and metabolism in drug development</i>
1995 (Mar)	Society of Toxicology, Baltimore, MD	<i>Why, when and how drugs should be tested as liver microsomal enzyme inducers</i>

Year	Institution or meeting	Title of presentation
1995 (Jun)	Annual meeting of the Society of Toxicologic Pathologists, San Diego, CA	<i>An overview of current cytochrome P450 technology for assessing the safety and efficacy of new materials</i>
1995 (Jun)	Upjohn Company, Kalamazoo, MI	<i>In vitro approaches to studying human drug metabolism</i>
1995 (Oct)	DuPont Merck Pharmaceuticals, Newark, DE	<i>In vitro techniques for studying drugs and new chemical entities as substrates, inhibitors and inducers of human cytochrome P450 enzymes</i>
1995 (Nov)	First International Symposium on Drug-Drug Interactions, St. Louis, MO	<i>Experimental approaches to evaluate drug interactions: Human microsomal systems</i>
1996		
1996 (Apr)	ASPET, Washington DC	<i>In vitro procedures for testing drugs as liver enzyme inducers</i>
1996 (May)	IBC Conference on Pharmacogenetics, Washington, DC	<i>Assessing drugs as liver enzyme inducers</i>
1996 (Jun)	Allergan, Irvine, CA	<i>FDA-driven research in drug metabolism</i>
1996 (Jul)	DuPont Merck Pharmaceuticals, Newark, DE	<i>In vitro procedures for testing drugs as liver enzyme inducers</i>
1996 (Sep)	University of Missouri, Kansas City, MO	<i>In vitro techniques for testing drugs and new chemical entities as substrates, inhibitors and inducers of human P450 enzymes</i>
1996 (Oct)	Swedish Association of the Pharmaceutical Industry Workshop, Stockholm, Sweden	<i>Availability and preservation of human tissues</i>
1996 (Oct)	International Society for the Study of Xenobiotics (ISSX), 7th Annual North American Meeting, NC	<i>Evaluating drugs and new chemical entities as inhibitors of human P450 enzymes</i>
1996 (Oct)	American Association for Pharmaceutical Sciences (AAPS), Seattle, WA	<i>Introduction to cytochrome P450 (part of an AAPS continuing education course)</i>
1996 (Dec)	IBC Conference on Pharmacogenetics, Washington, DC	<i>Enzyme induction: Assessing the potential for drug interactions</i>
1997		
1997 (Feb)	US-FDA (Food & Drug Administration) Washington, DC	<i>Introduction to cytochrome P450 (and Evaluating drugs and new chemical entities as inducers and suppressors of human P450 enzymes (presented with Dr. Madan).</i>
1997 (Mar)	Silicon Prairie Technology Association (SPTA), Kansas City, KS	<i>A brief overview of XenoTech</i>
1997 (Apr)	Merck, Rahway, NJ	<i>In vitro techniques for testing drugs and new chemical entities as substrates, inhibitors and inducers of human P450 enzymes</i>

Year	Institution or meeting	Title of presentation
1997 (Apr)	Merck, West Point, NJ	<i>Introduction to cytochrome P450 (repeat of the AAPS continuing education course)</i>
1997 (Oct)	ISSX, Hilton Head, SC	<i>A primer on reaction phenotyping: Do's and Don'ts for characterizing P450 activity: An infomercial</i>
1997 (Nov)	Allergan, Irvine, CA	<i>In vitro techniques for studying drugs and new chemical entities as substrates, inhibitors and inducers of human P450 enzymes</i>
1997 (Dec)	Astra Hässle AB, Mölndal, Sweden	<i>In vitro studies of drug interactions with terfenadine</i>
1997 (Dec)	IBC Conference on Drug-Drug Interactions, Washington, DC	<i>Evaluating P450 enzyme induction/ suppression in cultured human hepatocytes</i>
1998		
1998 (Feb)	Intercardia-Astra Merck, Wayne, PA	<i>In vitro studies of bucindolol metabolism</i>
1998 (May)	Boehringer Ingelheim, Ridgefield, CT	<i>Drug metabolism course – Enzymology</i>
1998 (Jun)	Japanese Society of Toxicology, Nagoya, Japan	<i>The use of human-derived tissues in drug discovery and development</i>
1998 (Jun)	Special seminars with Drs. Yoshihiko Funae and Tetsuo Satoh in Osaka and Yokohama, Japan	<i>The use of human-derived tissues in drug discovery and development</i>
1998 (Jul)	Cell Therapeutics Inc., Seattle, WA	<i>Evaluating lisofylline as a substrate and inhibitor of human P450 enzymes</i>
1998 (Aug)	AAPS Short Course, Arlington, VA	<i>Cytochrome P450</i>
1998 (Sep)	Inaugural Land o' Lakes Conference on Drug Metabolism, Merrimac, WI	<i>P450 induction in human and rat hepatocytes</i>
1998 (Oct)	Eli Lilly and Company, Indianapolis, IN	<i>Carboxylesterases: Structure, regulation, and role in xenobiotic metabolism</i>
1998 (Dec)	Allergan, Irvine, CA	<i>P450 Induction in human hepatocytes</i>
1999		
1999 (Mar)	Wyeth-Ayerst, New York, NY	<i>In vitro techniques for screening new chemical entities during drug discovery and development. Cancelled</i>
1999 (Apr)	Kansas City Discussion Group of Pharmaceutical and Allied Scientists, Kansas City, KS	<i>An after-dinner discourse on the great scientific discoverers, a hodgepodge of curious facts, and something my grandfather once told me</i>

Year	Institution or meeting	Title of presentation
1999 (Sep)	Allergan, Irvine, CA	<i>Carboxylesterases: Structure, regulation, and role in xenobiotic metabolism</i>
1999 (Oct)	Pharmaceutical Education and Research Institute (PERI), Arlington, VA	<i>Drug Metabolism and Drug Development: P450-Dependent Metabolism</i>
1999 (Oct)	Silicon Prairie Technology Association's BioScience Network, Kansas City, KS	<i>Current Trends in Financing a Biotech Company. Panel discussant on Development Stage Companies</i>
2000		
2000 (Feb)	European Center of Pharmaceutical Medicine (ECPM), Basel, Switzerland	<i>Drug Metabolism in Health and Disease-Cancelled because of bad weather</i>
2000 (Feb)	Kaufmann Foundation, Kansas City, MO	<i>Guest speaker, the Fast Track II course for entrepreneurs</i>
2000 (Aug)	Kaufmann Foundation, Kansas City, MO	<i>Guest speaker, the Fast Track II course for entrepreneurs</i>
2000 (Sep)	Allergan, Irvine, CA	<i>Metabolism of imidazole- and imidazoline-containing drugs</i>
2000 (Oct)	ISSX, Indianapolis, IN	<i>In vitro applications of fresh and cryopreserved human hepatocytes in drug metabolism and drug discovery</i>
2000 (Nov)	Japanese Society for Alternatives to Animal Experimentation (JSAAE), Ichikawa, Japan.	<i>Significance and problems of high-throughput screening (HTS) of enzyme inducers</i>
2000 (Nov)	Nippon Shinyaku, Shionogi, Sankyo, Sumitomo Chemical, Tanabe and Yamanouchi (six pharmaceutical companies in Japan)	<i>In vitro applications of fresh and cryopreserved hepatocytes in drug metabolism and discovery</i>
2000 (Dec)	TEBU, Paris, France	<i>An overview of XenoTech's products and services</i>
2001		
2001 (Feb Mar)	CBI's 2nd Annual Conference on Predicting Drug Metabolism, Philadelphia, PA Roche, Palo Alto, CA	<i>Application of bDNA technology and cryo-preserved hepatocytes to screen for enzyme induction</i>
2001 (Apr)	Pharmacia, Skokie, IL	<i>Application of in vitro drug metabolism techniques to support drug discovery and drug development</i>
2001 (Apr)	OSI Pharmaceuticals, Long Island, NY	<i>In vitro assays for metabolic enzyme induction and inhibition: Strategies and potential pitfalls</i>
2001 (May)	Kaufmann Foundation, Kansas City, MO	<i>Guest speaker at the Science and Technology Commercialization Forum</i>
2001 (May)	Purdue Pharma LP, Ardsley, NY	<i>Comparison of different in vitro systems for DMPK studies in drug discovery and drug development</i>

Year	Institution or meeting	Title of presentation
2001 (May)	Aventis, Bridgewater, NJ	<i>Comparison of different in vitro systems for DMPK studies in drug discovery and drug development</i>
2001 (Jun)	CHI's Eighth Annual HTT Expo, Philadelphia, PA	<i>ADME screening with hepatocytes</i>
2001 (Jun)	National Disease Research Institute (NDRI), Philadelphia, PA	<i>Human liver and its impact on drug safety</i>
2001 (Jun)	Glaxo-Smith-Kline (GSK), Research Triangle Park, NC	<i>Human hepatocytes and other in vitro systems to support drug discovery and development</i>
2001 (Jun)	Drew University Course on <i>Designing Safe Drugs: Integration of Biotransformation Studies in Drug Discovery & Development</i> . Princeton, NJ.	<i>Cytochrome P450: Impact on drug safety/efficacy and in vitro methods to assess it</i>
2001 (Jun)	North Jersey Drug Metabolism Discussion Group, Princeton, NJ	<i>Human hepatocytes: Hope, hype and hoey</i>
2001 (Aug)	Pfizer, Ann Arbor, Michigan	<i>Application of in vitro drug metabolism to drug discovery and development: Industrial and FDA perspective</i>
2001 (Sep)	Pfizer, Ann Arbor, MI	<i>A short course in drug metabolism</i>
2001 (Sep)	Kansas City Discussion Group of Pharmaceutical and Allied Scientists, Kansas City, MO	<i>An after-dinner discourse on the great scientific discoverers, a hodgepodge of curious facts, and something my grandfather once told me</i>
2001 (Sep)	Teijin and other pharmaceutical companies in Japan	<i>Assessing enzyme induction in vitro: An industrial and regulatory perspective</i>
2001 (Sep)	Teijin, Tokyo, Japan	<i>CYP1A1 enzyme induction</i>
2001 (Oct)	Hepatocyte Users Group (HUG), London, England	<i>The application of bDNA technology to evaluate enzyme induction in primary cultures of human and rat hepatocytes</i>
2001 (Oct)	Japanese Society for the Study of Xenobiotics (JSSX), Japan	<i>Enzyme induction: Its assessment in human hepatocytes and its impact on the drug approval process</i>
2001 (Oct)	Ajinomoto and other pharmaceutical companies in Japan	<i>Assessing enzyme induction in vitro: An industrial and regulatory perspective</i>
2002		
2002 (Jan)	Hokkaido University, Sapporo, Japan	<i>Carboxylesterases: An interesting diversion from our studies on cytochrome P450</i>
2002 (Jan)	CHI's conference on Drug Discovery, Japan	<i>Evaluating drugs and NCE's as enzyme inducers: Application of cultured hepatocytes and branched DNA (bDNA) technology</i>

Year	Institution or meeting	Title of presentation
2002 (Jan)	Daiichi, Meiji, Taisho and Teijin (four pharmaceutical companies in Japan)	<i>(1). Isolation of human hepatocytes for enzyme induction studies and cryopreservation. (2) Evaluating drugs and NCE's as cytochrome P450 inhibitors</i>
2002 (Jan)	Incara Pharmaceuticals, Raleigh, NC	<i>XenoTech: An overview of the company and its products and services</i>
2002 (Feb)	CBI's 3 rd Annual Predictive ADME/Tox Conference, Philadelphia, PA	<i>In vitro systems to evaluate the metabolic stability of drugs</i>
2002 (Feb)	University of Kansas Medical Center, Kansas City, KS	<i>XenoTech: An overview of the company and its industry</i>
2002 (May)	Lion Bioscience, San Diego, CA	<i>Application of in vitro drug metabolism to drug discovery and development: Industrial and regulatory perspectives</i>
2002 (May)	Human Animal Bridge (annual conference), Tokyo, Japan	<i>In vitro approaches to enzyme induction</i>
2002 (Jun)	Aventis Workshop on Cytochrome P450, Frankfurt, Germany	<i>Strategies to assess CYP induction drug-drug interaction potential: in vitro perspective</i>
2002 (Jun)	UCB Pharma, Boston, MA	<i>The application of branched DNA (bDNA) technology to study enzyme induction in cultured hepatocytes</i>
2002 (Jul)	Microsomes & Drug Oxidations (MDO) meeting in Sapporo, Japan	<i>Enzyme induction: Best practices and regulatory considerations.</i>
2002 (Jul)	Kyowa Hakko, Mochida, Ono and Yamanouchi (four pharmaceutical companies in Japan)	<i>Evaluating drugs and NCE's as cytochrome P450 inhibitors and P450 inducers (2 talks)</i>
2002 (Sep)	Pfizer, Sandwich, Kent, England	<i>The role of human hepatocytes, subcellular fractions and recombinant enzymes in pre-clinical ADMET studies</i>
2002 (Oct)	ISSX, Orlando, Florida	<i>Effects of gender, age, ethnicity and cirrhosis on human liver cytochrome P450 (CYP) enzyme activity and inducibility</i>
2002 (Nov)	Human Animal Bridge (annual meeting for young scientists), Tokyo, Japan	<i>The use of human hepatocytes and related in vitro systems for evaluating enzyme induction and chemical toxicity</i>
2003		
2003 (Mar)	Hepatocyte Users Group (HUG), Aberdeen, Scotland	<i>Effects of gender, age, ethnicity and cirrhosis on human liver cytochrome P450 (CYP) enzyme activity and inducibility (presentation made by David Steen)</i>
2003 (May)	ACS PerSpectives – ADMET in the 21st Century. St. Petersburg, FL	<i>Contemporary tools for enzyme induction</i>

Year	Institution or meeting	Title of presentation
2003 (Jun)	Drew University Course on Designing Safe Drugs: Integration of Biotransformation Studies in Drug Discovery and Development. Madison, NJ.	<i>Cytochrome P450: Impact on drug safety/efficacy and in vitro methods to assess it</i>
2003 (Aug)	Nagawa Forum (Nagano Prefecture), Tokyo, Japan	<i>The assessment of cellular toxicity in vitro and its relevance to clinically observed organ specific toxicity including hepatotoxicity</i>
2003 (Oct)	Daiichi, Dainippon, Japan Tobacco, Mitsubishi Welpharma, Taisho (five pharmaceutical companies in Japan)	<i>Immortalization of hepatocytes from a human donor – retention of near-normal morphology and function</i>
2003 (Oct)	Japanese Pharmaceutical Manufacturers Association (JMPA) conference on Bio-markers, Tokyo, Japan	<i>The assessment of human cytochrome P450 induction and hepatocellular toxicity in vitro</i>
2003 (Oct)	University of Queensland, Brisbane, Australia	<i>Incubating a company (XenoTech) in academia: The good, the bad and the ugly</i>
2003 (Oct)	ISSX, Providence, RI	<i>Immortalization of hepatocytes from a human donor – retention of near-normal morphology and function</i>
2003 (Oct)	University of Kansas (annual Technology Awards dinner). Lawrence, KS	<i>Award recipient and after-dinner speaker</i>
2003 (Nov)	GSK, Research Triangle Park, NC	<i>Induction of the major cytochrome P450 enzymes in immortalized human hepatocytes (Fa2N-4 cells)</i>
2004		
2004 (Jan)	National Disease Research Institute (NDRI) (annual board meeting). Philadelphia. PA	<i>XenoTech-NDRI: Making drugs safer and effective for everyone</i>
2004 (Feb)	CBI's 5th Annual Predictive ADME/Tox Conference, Philadelphia, PA	<i>Induction of the major cytochrome P450 enzymes in immortalized human hepatocytes (Fa2N-4 cells)</i>
2004 (Feb)	Hoffmann-La Roche (Nutley), Aventis (Bridgewater) and Bristol-Myer Squib (three pharmaceutical companies)	<i>Immortalized human hepatocytes: A new in vitro approach to enzyme induction and other ADME-Tox studies</i>
2004 (Feb)	ISE's 4th International Conference on Early Toxicity Screening, San Diego, California	<i>Immortalized human hepatocytes: A new in vitro approach to early enzyme induction and hepatotoxicity screening</i>
2004 (Mar)	European Center of Pharmaceutical Medicine (ECPM), Basel, Switzerland	<i>Drug metabolism in health and disease</i>
2004 (Mar)	Hoffmann-La Roche, Basel, Switzerland	<i>Immortalized human hepatocytes: A new in vitro approach to enzyme induction and other ADME-Tox studies</i>
2004 (Mar)	Boehringer Ingelheim, n/r Frankfurt, Germany	<i>An overview of in vitro approaches to drug metabolism and drug interactions (CYP inhibition and induction)</i>

Year	Institution or meeting	Title of presentation
2004 (Apr)	Southern California Drug Metabolism Discussion Group (annual meeting), San Diego, CA	<i>Immortalized human hepatocytes: A new in vitro approach to enzyme induction and toxicity studies</i>
2004 (May)	CHI's Conference on Cell-Based Assays for HTS, Philadelphia, PA	<i>Immortalized human hepatocytes: A new in vitro approach to early compound screening</i>
2004 (Jun)	ISE's 7th International Conference on Drug-Drug Interactions, San Diego, CA	<i>Immortalized and fresh human hepatocytes: Use and performance in metabolism, induction and toxicity screens</i>
2004 (Jun)	Eisai Co. Ltd, Tsukuba-Shi, Ibaraki, Japan	<i>Immortalized human hepatocytes: Use and performance in metabolism, induction and toxicity screening</i>
2004 (Jun)	Kissei Pharmaceutical Company, Matsumoto City, Nagano Prefecture, Japan	<i>An overview of selected products and services from XenoTech</i>
2004 (Jul)	Microsomes & Drug Oxidations symposium, Mainz, Germany	<i>Immortalized human hepatocytes and other new products and services from XenoTech (an infomercial)</i>
2004 (Aug)	Bristol-Myers Squibb, Princeton, NJ	<i>CYP inhibition and CYP induction studies at XenoTech (presented with Brian Ogilvie, Paul Toren and Florence Ndikum-Moffor)</i>
2004 (Sep)	Sepracor, Marlborough, MA	<i>Overview of Phase 2 metabolism from a drug development and regulatory perspective</i>
2004 (Oct)	Abbott, Abbott Park, IL	<i>Structural alerts as guides to drug discovery and development</i>
2004 (Oct)	ISE's conference on <i>In Vitro</i> ADMET Technologies, Cambridge, MA	<i>Latest assessment of Fa2N-4 immortalized human hepatocytes in drug discovery and development</i>
2004 (Nov)	Sankyo Co. Ltd, Shinagawa-Ku, Tokyo, Japan	<i>In vitro approaches to studying cytochrome P450 inhibition and reaction phenotyping (enzyme mapping)</i>
2004 (Dec)	CHI's conference on <i>In vitro</i> Screens in Drug Metabolism, Lake Buena Vista, FL	<i>The use of Fa2N-4 immortalized human hepatocytes for in vitro screening</i>
2005		
2005 (Jan)	Neurocrine, San Diego, CA	<i>Latest assessment of Fa2N-4 immortalized human hepatocytes in drug discovery and development</i>
2005 (Feb)	Symposium for Japanese Scientists, Lenexa, KS	<i>Meeting organizer and chairman</i>
2005 (Feb)	Schering Plough Research Institute, Kenilworth, NJ	<i>The effects of age, gender, ethnicity and other factors on cytochrome P450 function and induction</i>
2005 (Mar)	Tebu-bio, Paris, France	<i>Overview of XenoTech's products, services and business</i>

Year	Institution or meeting	Title of presentation
2005 (Mar)	Almirall, Barcelona, Spain	<i>Pre-clinical drug discovery and development: Structural alerts and in vitro ADMET studies</i>
2005 (Mar)	Almirall, Barcelona, Spain	<i>Enzyme induction in primary cultures of rat and human hepatocytes</i>
2005 (Mar)	Sankyo Co. Ltd., Shinagawa-Ku, Tokyo, Japan	<i>Glucuronidation from a drug development and regulatory perspective</i>
2005 (Mar)	Sankyo Co. Ltd., Shinagawa-Ku, Tokyo, Japan	<i>The use of Fa2N-4 immortalized human hepatocytes for in vitro screening</i>
2005 (Mar)	Pharmaceutical companies in Japan (Dainippon, Sumitomo, Taiho, Shionogi)	<i>An overview of XenoTech's products and services</i>
2005 (Mar)	Japanese Pharmaceutical Society (annual meeting), Tokyo, Japan	<i>Trends in the in vitro use of human-derived material to support drug discovery and development</i>
2005 (Apr)	Department of Commerce, Topeka, KS (Exporter of the Year presentation)	<i>Finalist Presentation: XenoTech LLC</i>
2005 (May)	Taisho Pharmaceutical Company, Saitama, Japan	<i>Cytochrome P450 and UGT enzymes: Recent advances in methodology and the FDA's perspective</i>
2005 (May)	Human-Animal Bridge (Annual Meeting) in Tokyo, Japan	<i>Immortalized human hepatocytes (Fa2N-4 cells): A new tool to assess enzyme induction</i>
2005 (May)	Human-Animal Bridge (Annual Meeting) in Tokyo, Japan	<i>Cytochrome P450 and UGT enzymes: Recent advances in methodology and the FDA's perspective (Luncheon Seminar)</i>
2005 (May)	Nosan Corporation. Special seminar for pharmaceutical scientists. Yokohama, Japan	<i>Drug-induced liver disease and immortalized human hepatocytes (Fa2N-4 cells)</i>
2005 (May)	Sigma Xi Annual Meeting, University of Kansas Medical Center, Kansas City, KS	<i>From KUMC (academia) to XenoTech (industry): A beacon for capitalism or a red light over the ivory tower door?</i>
2005 (Jun)	XenoTech's inaugural symposium (attended by pharmaceutical scientists from Japan and America). Kansas City, MO	<i>Organizer and chairman. Cytochrome P450 induction in primary and immortalized human hepatocytes</i>
2005 (Aug)	WIL Research Laboratories, Ashland, OH	<i>Enzyme induction studies in rats and other laboratory animals ex vivo: Part 1: Toxicological implications. Part 2: Clinical implications</i>
2005 (Dec)	Department of Pharmacology, Toxicology and Therapeutics, University of Kansas Medical Center, Kansas City, KS	<i>Drug-drug interactions: The role of CYP, UGT and OATP in the lethal interaction between gemfibrozil and cerivastatin</i>
2006		

Year	Institution or meeting	Title of presentation
2006 (Jan)	Institute for Diabetes Discovery, Hartford, CT	<i>Drugs as victims and perpetrators of drug interactions. Part 1: Why and how we conduct reaction phenotyping studies. Part 2: Why and how we conduct CYP inhibition and induction studies</i>
2006 (Feb)	Otsuka Pharmaceutical Company, Japan	<i>XenoTech's products and services. Drugs as victims and perpetrators of drug interactions. Why and how we conduct CYP induction studies</i>
2006 (Feb)	Taiho Pharmaceutical Company, Japan Astellas Pharmaceutical Company, Tokyo, Japan Eisai Pharmaceutical Company, Tsukuba-Shi, Ibaraki, Japan	<i>Drugs as victims and perpetrators of drug interactions. Part 1: CYP induction in human hepatocytes. Part 2: CYP inhibition – the unusual but lethal interaction between gemfibrozil and cerivastatin</i>
2006 (Feb)	Taisho Pharmaceutical Company, Saitama, Japan	<i>Enzyme induction in primary and immortalized human hepatocytes: Advances, and new approaches to extrapolating induction data</i>
2006 (Feb)	Mitsubishi Pharma, Tokyo, Japan	<i>Drugs as victims and perpetrators of drug interactions. Why and how we conduct reaction phenotyping studies</i>
2006 (Feb)	Daiichi-Sankyo Pharmaceutical Company, Japan	<i>Drug-drug interactions: The role of CYP, UGT and OATP in the lethal interaction between gemfibrozil and cerivastatin</i>
2006 (Feb)	European Center of Pharmaceutical Medicine (ECPM), Basel, Switzerland	<i>Drug metabolism in health and disease</i>
2006 (Mar)	Society of Toxicology (annual meeting), San Diego, CA	<i>Toxicity of human metabolites – Invited participant in panel discussion</i>
2006 (Mar)	Abbott Bio-Research Center, Worcester, MA	<i>Drugs and victims and perpetrators: The basis for in vitro assays (reaction phenotyping, CYP inhibition and CYP induction)</i>
2006 (Mar)	Genentech, San Francisco, CA	<i>Drugs and victims and perpetrators: The basis for in vitro assays: Part A: Enzyme induction</i>
2006 (Mar)	Nektar, San Francisco, CA	<i>Drugs and victims and perpetrators: The basis for in vitro assays (reaction phenotyping, CYP inhibition and CYP induction)</i>
2006 (Apr)	Vanda Pharmaceuticals, Rockville, MD	<i>Drugs and victims and perpetrators: The basis for in vitro assays (reaction phenotyping, CYP inhibition and CYP induction)</i>
2006 (May)	CHI's World Pharmaceutical Congress, Philadelphia, PA	<i>Current approaches to drug-drug interactions</i>
2006 (Jul)	XenoTech's Annual Symposium, Kansas City, KS	<i>Pharmacological and toxicological implications of enzyme induction</i>

Year	Institution or meeting	Title of presentation
2006 (Aug)	Allergan, Irvine, CA	<i>The application of in vitro drug-drug interaction studies in drug development</i>
2006 (Oct)	Central States Society of Toxicology, Kansas City, KS	<i>Drug-drug interactions: Identifying victims and perpetrators during pre-clinical drug development</i>
2006 (Nov)	Taisho Pharmaceutical Company, Saitama, Japan	<i>Structural alerts in drug development: Some strategies to minimize pharmacokinetic, toxicity and drug interaction liabilities</i>
2006 (Nov)	Nosan ADME-Tox Symposium, Yokohama, Japan	<i>Drug-drug interactions: Identifying victims and perpetrators during pre-clinical drug development</i>
2006 (Nov)	Safety Evaluation Forum, Tokyo, Japan	<i>Drug-induced liver disease (DILI): Do we know enough to avoid idiosyncratic toxicity?</i>
2007		
2007 (Mar)	The Leadership Forum, Kansas City, KS	<i>Stem cells and other new life sciences technologies</i>
2007 (Mar)	Forest Research Institute (Forest Laboratories), Jersey City, NJ	<i>Structural alerts in drug development: Some strategies to minimize pharmacokinetic, toxicity & drug interaction liabilities</i>
2007 (May)	American Chemical Society - Mid-Atlantic Regional Meeting (ACS-MARM), Ursinus College, Collegeville, PA	<i>Induction of drug-metabolizing enzymes: In vitro studies, IVIVC and the emerging role of xenosensors in endobiotic homeostasis</i>
2007 (May)	Delaware Valley Drug Metabolism Discussion Group (DVDMDG) and Rozman Symposium, Philadelphia, PA	<i>The unusual mechanism of the sometimes lethal pharmacokinetic interaction between gemfibrozil and cerivastatin (now withdrawn from the market)</i>
2007 (June)	Teva Pharmaceuticals – Inaugural ADME Workshop, Budapest, Hungary	<i>In vitro techniques to assess the victim and perpetrator potential of drug candidates: The basis for reaction phenotyping, enzyme inhibition & enzyme induction</i>
2007 (June)	Solvo, Budapest, Hungary	<i>The unusual mechanism of the sometimes lethal pharmacokinetic interaction between gemfibrozil and cerivastatin</i>
2007 (Oct)	Japan Tobacco (Pharmaceutical Division), Osaka, Japan Shionogi Pharmaceutical Company, Osaka, Japan Otsuka Pharma, Tokushima, Japan Eisai Pharmaceutical Company, Tsukuba-Shi, Ibaraki, Japan Astellas Pharmaceutical Company, Tokyo, Japan	<i>In vitro techniques to assess the victim and perpetrator potential of drug candidates: The basis for reaction phenotyping, enzyme inhibition & enzyme induction</i>
2007 (Nov)	Xenobiotic Laboratories 20 th Anniversary Symposium, Princeton, NJ	<i>Cytochrome P450 induction: Mechanism, interpretation, and clinical significance</i>
2007 (Nov)	Teva Pharmaceutical Industries Ltd. Neyanya (near Tel Aviv), Israel	<i>A three-part, all-day course on drug metabolism</i>

Year	Institution or meeting	Title of presentation
2008		
2008 (May)	North Jersey Drug Metabolism Discussion Group, Somerset, New Jersey	<i>Ten things you may not know about ADME-Tox</i>
2008 (May)	World Pharmaceutical Congress, Philadelphia, PA	<i>Role of cytochrome P450 enzymes in drug-drug interactions and the clinical implications</i>
2008 (Jul)	XenoTech's Symposium, Philadelphia, PA	<i>State of the art in vitro drug-drug interaction studies</i>
2008 (Oct)	Tebu-bio's Symposium, Paris, France	<i>In vitro techniques to assess the victim and perpetrator potential of drug candidates: the basis for reaction phenotyping, enzyme inhibition, enzyme induction and drug transporter studies.</i>
2008 (Oct)	JSSX meeting, Kumamoto, Japan	<i>New regulatory and experimental developments in the in vitro approaches to assess the victim and perpetrator potential of drug candidates</i>
2009		
2009 (Feb)	University of Kansas, Lawrence, KS	<i>The unusual mechanism of the sometimes lethal pharmacokinetic interaction between gemfibrozil and cerivastatin</i>
2009 (Mar)	Schering Plough Research Institute, Kenilworth, NJ	<i>In vitro CYP inhibition studies: Automated procedures, mechanistic follow-up studies and system-dependent outcomes</i>
2009 (Apr)	Hoffmann-La Roche, Nutley, NJ	<i>Structural alerts for the formation of reactive metabolites including acyl glucuronides</i>
2009 (Apr)	University of Kansas Medical Center – Liver Center 2009 Symposium, Kansas City, KS	<i>Evaluating the victim and perpetrator potential of drugs (right here in Kansas City)</i>
2009 (Jun)	AstraZeneca, Waltham, MA	<i>New developments in the in vitro assessment of the victim & perpetrator potential of drug candidates</i>
2009 (Jun)	Abbott Laboratories, Abbott Park, IL	<i>Cytochrome P450 (CYP) inhibition: Unexpected consequences of experimental design and examples of in vitro system-dependent inhibition</i>
2009 (Jul)	AstraZeneca, Charnwood, England	<i>In vitro approaches to evaluate the victim and perpetrator potential of drug candidates</i>
2009 (Jul)	University of Manchester, England	<i>Cytochrome P450 (CYP) inhibition: Unexpected consequences of experimental design and examples of in vitro system-dependent inhibition</i>
2009 (Jul)	AstraZeneca, Alderly Park, England	<i>In vitro approaches to evaluate the victim and perpetrator potential of drug candidates</i>

Year	Institution or meeting	Title of presentation
2009 (Jul)	Antisoma, London, England GSK, Ware, England Cancer Research Technology, London, England Argenta Discovery, Harlow, England	<i>In vitro approaches to evaluate the victim and perpetrator potential of drug candidates</i>
2009 (Oct)	Genentech, San Francisco, CA Gilead, San Francisco, CA Exelexis, San Francisco, CA Intermune, San Francisco, CA élan, San Francisco, CA	<i>System-dependent inhibition of cytochrome P450: Hepatocytes versus human liver microsomes and the design of CYP inhibition experiments</i>
2009 (Oct)	All SAC Kaizen Meeting, Winchester, KY	<i>Overview of XenoTech</i>
2009 (Oct)	ISSX (annual meeting), Baltimore, MD	<i>Ten things you may not know about CYP inhibition</i>
2009 (Nov)	Lilly, Indianapolis, IN	<i>Ten things you may not know about CYP inhibition</i>
2009 (Nov)	iBiopharm conference organized for representatives from over 50 Korean companies. Seoul, South Korea	<i>What does the FDA require to evaluate the victim and perpetrator potential of drug candidates and how does XenoTech achieve this goal?</i>
2009 (Nov)	LG Life Sciences, Seoul, South Korea	<i>Structural alerts for the formation of reactive metabolites including acyl glucuronides</i>
2009 (Nov)	Yuhan Research Institute, Seoul, South Korea	<i>Cytochrome P450 induction: Mechanism, in vitro approaches, interpretation and clinical significance</i>
2009 (Nov)	Dong-A Pharm, Seoul, South Korea	<i>What does the FDA require to evaluate the victim and perpetrator potential of drug candidates and how does XenoTech achieve this goal?</i>
2009 (Nov)	JSSX (annual meeting), Kyoto, Japan	<i>System-dependent inhibition of cytochrome P450 (CYP) enzymes (human liver microsomes versus hepatocytes)</i>
2009 (Nov)	Asahi Kasei Pharm, Tokyo, Japan Chugai Pharm, Tokyo, Japan Daiichi-Sankyo, Tokyo, Japan Shionogi, Osaka, Japan Takeda, Osaka, Japan Tanabe-Mitsubishi, Tokyo, Japan	<i>Ten things you may not know about CYP inhibition</i>
2009 (Dec)	Sanofi-Aventis, Frankfurt, Germany	<i>What does the FDA require to evaluate the victim and perpetrator potential of drug candidates and how does XenoTech achieve this goal?</i>

Year	Institution or meeting	Title of presentation
2009 (Dec)	Boehringer-Ingelheim, Vienna, Austria	<i>Ten things you may not know about CYP inhibition</i>
2009 (Dec)	GSK, Verona, Italy	<i>What does the FDA require to evaluate the victim and perpetrator potential of drug candidates and how does XenoTech achieve this goal?</i>
2009 (Dec)	Siena Biotech, Siena, Italy	<i>Ten things you may not know about CYP inhibition</i>
2010		
2010 (Mar)	Merck–Serono, Geneva, Switzerland Merck KGa, Grafing, Germany	<i>Part 1. Ten things you may not know about CYP inhibition. (Presented as a webinar)</i> <i>Part 2. What does the FDA require to evaluate the victim and perpetrator potential of drug candidates and how does XenoTech achieve this goal? (Presented as a webinar)</i>
2010 (Mar)	AstraZeneca, Wilmington, DE Bristol-Myers Squibb (BMS), Princeton, NJ Novartis, East Hanover, NJ	<i>What does the FDA require to evaluate the victim and perpetrator potential of drug candidates and how does XenoTech achieve this goal?</i>
2010 (Apr)	IAMI Fellows Program, University of Kansas, Lawrence, KS	<i>Ten things I learned about incubating a start-up company from academia</i>
2010 (Apr)	Active Biotech, Lund, Sweden Karobio, Huddinge, Sweden NeuroSearch, Gothenberg, Sweden Orexo, Uppsala, Sweden	<i>Ten things you may not know about CYP inhibition</i>
2010 (Apr)	AstraZeneca, Lund, Sweden	<i>Victims & Perpetrators ... and a few things you may not know about CYP inhibition</i>
2010 (Apr)	Lundbeck, Copenhagen, Denmark	<i>Structural alerts for the formation of reactive metabolites including acyl glucuronides</i> <i>Ten things you may not know about CYP inhibition</i>
2010 (Jun)	DDI Workshop, Marbach Castle, Germany	<i>System-dependent inhibition: When should CYP inhibition studies be conducted in hepatocytes?</i>
2010 (Jun)	Nycomed Konstanz, Germany	<i>In vitro approaches to assessing the victim and perpetrator potential of drug candidates: Selected topics</i>
2010 (Jun)	Recordati, Milan, Italy PharmEste, Milan, Italy	<i>Victims & Perpetrators ... and a few things you may not know about CYP inhibition</i>

Year	Institution or meeting	Title of presentation
2010 (Jun)	ESI's 13 th DDI Conference, Seattle, WA	<i>Rules for evaluating drug candidates as system-dependent inhibitors and metabolism-dependent inhibitors of cytochrome P450 (CYP) enzymes</i>
2010 (Jul)	SMi ADMET Conference, London, England	<i>System-dependent inhibition of cytochrome P450 (CYP) enzymes: Common misconceptions and errors</i>
2010 (Jul)	Celgene, San Diego, CA	<i>Drugs as victims and perpetrators: Ten things you may not know about in vitro testing</i>
2010 (Nov)	GSK – Research Triangle Park, NC	<i>What the FDA requires to evaluate the victim and perpetrator potential of drug candidates</i>
2010 (Nov)	Boehringer Ingelheim, Ridgefield, CT	<i>Ten things you may not know about CYP inhibition</i>
2010 (Nov)	Antisoma, Cambridge, MA Biogen, Cambridge, MA Ironwood Pharmaceuticals, Cambridge, MA	<i>Evaluating the victim & perpetrator potential of drug candidates: Lysosomal trapping</i>
2010 (Nov)	Millennium Pharmaceuticals, Cambridge, MA	<i>Evaluating the victim & perpetrator potential of drug candidates: Enzyme Induction</i>
2010 (Nov)	Infinity Pharmaceuticals, Cambridge, MA	<i>What the FDA requires to evaluate the victim and perpetrator potential of drug candidates</i>
2010 (Nov)	Sanofi-Aventis, Frankfurt, Germany	<i>In vitro techniques to evaluate the victim and perpetrator potential of drug candidates</i>
2010 (Dec)	Astellas, Chuo-Ku (Tokyo), Japan Chugai Pharmaceutical Co., Shizuoka (Tokyo) Japan Dainippon-Sumitomo, Osaka, Japan Sekisui Medical Division, Tokai-mura, Ibaraki Prefecture, Japan Shionogi, Osaka, Japan Taisho Pharmaceutical Co., Tokyo, Japan Takeda, Osaka, Japan Tanabe-Mitsubishi, Chiba, Japan	<i>New developments in the in vitro evaluation of the victim & perpetrator potential of drug candidates</i>
2011		
2011 (Feb)	Antisoma, Cambridge, MA Biogen Idec, Cambridge, MA Genzyme, Cambridge, MA Infinity, Cambridge, MA Ironwood, Cambridge, MA Merck Research Laboratories, Cambridge, MA Millennium, Cambridge, MA Synta, Cambridge, MA	<i>Irreversible Inhibition of CYP2C19 by some but not all proton pump inhibitors and its relevance to the anti-platelet effect of clopidogrel (Plavix)</i>

Year	Institution or meeting	Title of presentation
2011 (Feb)	Novartis, Cambridge, MA	<i>New developments in the design of in vitro studies of CYP inhibition and drug metabolism in HLM and hepatocytes</i>
2011 (Feb)	Boehringer Ingelheim, Danbury, CT	<i>Evaluating the victim & perpetrator potential of drug candidates: Enzyme Induction</i>
2011 (Apr)	Bristol Myers Squibb Princeton, NJ	<i>Evaluating the victim & perpetrator potential of drug candidates: Enzyme Induction</i> <i>Irreversible inhibition of CYP2C19 by some but not all proton pump inhibitors and its relevance to the anti-platelet effect of clopidogrel (Plavix)</i>
2011 (Apr)	Forest Research, Commack, NY	<i>System-dependent inhibition of cytochrome P450 (CYP) enzymes</i> <i>Reaction phenotyping for CYP and UGT enzymes and the importance of victim potential</i> <i>In vitro evaluation of drug candidates for transporter victim & perpetrator potential</i>
2011 (Apr)	North Jersey Drug Metabolism Discussion Group (NJDMDG), Somerset, NJ AstraZeneca, Waltham, MA	<i>Irreversible Inhibition of CYP2C19 by some but not all proton pump inhibitors and its relevance to the anti-platelet effect of clopidogrel (Plavix)</i>
2011 (Apr)	Genzyme, Cambridge, MA	<i>Evaluating the victim & perpetrator potential of drug candidates: Lysosomal Trapping</i>
2011 (Apr)	SK Life Sciences, Fairlawn, NJ	<i>Reaction phenotyping for CYP and UGT enzymes and the importance of victim potential</i>
2011 (May)	Second International DDI Workshop, Marbach Castle, Germany	<i>In vitro approaches to assessing the enzyme-suppressing effects of large molecule drugs</i>
2011 (May)	Ferring, Copenhagen, Denmark Lundbeck, Copenhagen, Denmark Novartis, Basel, Switzerland	<i>The new regulatory emphasis on drug transporters and the often neglected importance of lysosomal trapping</i>
2011 (May)	Lundbeck, Copenhagen, Denmark	<i>Structural alerts for the formation of reactive metabolites including acyl glucuronides</i>
2011 (May)	Nycomed, Konstanz, Germany	<i>Evaluating the victim & perpetrator potential of drug candidates: Lysosomal Trapping</i> <i>In vitro approaches to assessing the enzyme-suppressing effects of large molecule drugs</i>
2011 (May)	Roche, Basel, Switzerland	<i>New developments in the in vitro evaluation of CYP inhibition</i>

Year	Institution or meeting	Title of presentation
2011 (May)	Abbott, Abbott Park, IL	<i>Selected ADMET Topics: Part 1. System-dependent inhibition. Part 2. Lysosomal trapping, and CYP & UGT reaction phenotyping</i>
2011 (May)	Astellas, Skokie, IL	<i>Selected ADMET Topics: Part 1, Enzyme induction. Part 2. Structural alerts for toxicity and MDI of CYP enzymes. Part 3. System-dependent inhibition</i>
2011 (May)	Camargo, Cincinnati, OH	<i>Irreversible Inhibition of CYP2C19 by some but not all proton pump inhibitors and its relevance to the anti-platelet effect of clopidogrel (Plavix)</i>
2011 (May)	GSK, Research Triangle Park, NC	<i>Drug transport and lysosomal trapping: In vitro evaluation and their relevance to drug disposition and phospholipidosis</i>
2011 (May)	CoLucid, Research Triangle Park, NC	<i>Structural alerts and the in vitro assessment of drug candidates for CYP inactivation and the formation of reactive metabolites</i>
2011 (May)	RTI International, Research Triangle Park, NC	<i>Structural alerts for reactive metabolites and drug-drug interactions involving CYP inhibition, drug transport and lysosomal trapping</i>
2011 (May)	Scinexis, Research Triangle Park, NC	<i>New FDA regulations for in vitro DDI assessment</i>
2011 (May)	Viamet, Research Triangle Park, NC	<i>Assessing the victim & perpetrator potential of drug candidates: Interaction with transporters and inhibition of CYP enzymes</i>
2011 (May)	Research Triangle Park Drug Metabolism Discussion Group (RTP-DMDG), Raleigh-Durham, NC	<i>Irreversible Inhibition of CYP2C19 by some but not all proton pump inhibitors and its relevance to the anti-platelet effect of clopidogrel (Plavix)</i>
2011 (Jun)	ISE-ETS (Early Toxicity Screening), Seattle, WA	<i>Lysosomal trapping of lipophilic amines and its relationship to drug transporters and phospholipidosis</i>
2011 (Jul)	Gordon Research Conference Drug Metabolism, Holderness, NH	<i>Lysosomal trapping: Methods of investigation, pharmacokinetic consequences and toxicological implications</i>
2011 (Aug)	AstraZeneca, Wilmington, DE	<i>In vitro approaches to assess the enzyme-suppressing effects of therapeutic proteins (large drug molecules)(Presented by webinar)</i>
2012		
2012 (May)	Great Lakes Drug Metabolism Discussion Group, Kalamazoo, MI	<i>In vitro approaches to assess the enzyme-suppressing effects of therapeutic proteins</i>

Year	Institution or meeting	Title of presentation
2012 (May)	DDI 2012 – The 3rd International Workshop, Marbach Castle, Germany	<i>In vitro assessment of DDIs mediated by UDP-glucuronosyltransferases (UGTs): Many differences to cytochrome P450s</i>
2012 (July)	Gordon Research Conference on Drug Metabolism, Holderness, NH	<i>The impact of experimental design on the in vitro assessment of metabolism-dependent inhibition of CYP enzymes</i>
2012 (Sept)	Small Business Technology & Development Center (SBTDC) Tech Entrepreneur Speakers Program, Kansas City, MO	<i>Things I learned incubating a company from academia and selling it to Japanese competitor</i>
2012 (Oct)	Central States Society of Toxicology annual meeting – John Doull Award Talk – Manhattan, KS	<i>Unexpected surprises. Two serious drug interactions caused by cytochrome P450 inhibition that were not predicted from initial in vitro studies.</i>
2014		
2014 (May)	DDI 2014 – The 5 th International Workshop, Marbach Castle, Germany	<i>Drug metabolism versus drug transport: Out of the frying pan, into the fire. A structure-based process for deciding whether to conduct in vitro metabolism or transport studies first</i>
2014 (Oct)	Genentech, San Francisco, CA	<i>Enzyme induction in human-derived systems in vitro and in nonclinical species in vivo: Methods, meaning & management.</i> <i>In vitro approaches to assess the enzyme-suppressing effects of therapeutic proteins</i> <i>Drug metabolism versus drug transport: Out of the frying pan, into the fire. A structure-based process for deciding whether to conduct in vitro metabolism or transporter studies first</i>
2014 (Nov)	AAPS, San Diego, CA (speaker and one of four roundtable discussion leaders)	<i>The future of in vitro systems for the assessment of induction and suppression of enzymes and transporters.</i>
2015		
2015 (May)	DDI 2015 – The 6 th International Workshop, Marbach Castle, Germany	<i>The mystery surrounding the 3-hydroxylation of desloratadine: A bizarre case of a cytochrome P450 reaction that occurs in human hepatocytes but not in human liver microsomes</i>
2015 (June)	19th International Conference of Cytochrome P450 (19ICCP450). Tokyo, Japan	<i>The practical aspects of complying with regulatory guidelines on drug interactions: Some notable strengths and weaknesses of in vitro testing</i>
2016		
2016 (Oct)	Qualyst Transporter Solutions, Durham, NC	<i>Transporter lessons from bile acids and our ability to eat bacteria-infected food. A structure-based process for deciding whether to conduct in vitro metabolism or transport studies first</i>

Year	Institution or meeting	Title of presentation
2016 (Oct)	Epizyme, Cambridge, MA	<i>Lysosomal partitioning: Methods of investigation, pharmacokinetic consequences and toxicological implications</i>
2016 (Oct)	Spero Therapeutics, Cambridge, MA Concert Pharmaceuticals, Lexington, MA	<i>Use of Transporter Certified™ human hepatocytes for CYP induction studies: A case study of over-prediction of CYP induction, CYP suppression and cell toxicity</i>
2017		
2017 (Jan)	Teva Pharmaceuticals, Tel Aviv, Israel	<i>One-day (8-h) course on ADMET (absorption, distribution, metabolism, elimination and transport of drugs)</i>
2017 (May)	DDI 2017 – The 8 th International Workshop, Marbach Castle, Germany	<i>The mechanism and pharmacokinetic & toxicological consequences of ion partitioning of drugs into lysosomes</i>
2017 (Sept)	Qualyst-sponsored webinar on <i>CYP450 induction studies: Benefits of an in vitro hepatic model with functioning transporters</i>	<i>Stop conducting induction studies in constipated hepatocytes: Use transporter-certified hepatocytes</i>
2017 (Nov)	Qualyst (BioreclamationIVT)-sponsored webinar on the new FDA draft Guidance for Industry on <i>in vitro</i> drug-drug interactions	<i>The new FDA Guidance on in vitro drug-drug interaction (DDI) studies: How will it impact you?</i>
2017 (Dec)	Sekisui-XenoTech-sponsored webinar on the new FDA and PMDA draft guidelines on <i>in vitro</i> drug-drug interactions	<i>Comparison between the new US FDA and Japan PMDA in vitro DDI Guidance: Are we close to harmonization?</i>
2018		
2018 (May)	Research Triangle Park Drug metabolism Discussion Group (RTP-DMDG), Raleigh-Durham, NC	<i>A lifetime in drug metabolism & disposition: My top ten WTF moments</i>
2018 (May)	DDI 2018 – The 9 th International Workshop, Marbach Castle, Germany	<i>The new FDA in vitro metabolism- and transporter-mediated drug-drug interaction guidance – A perspective from practice</i>
2018 (June)	Alkermes, Waltham, MA	<i>The role of non-CYP pathways in drug clearance</i>
2018 (Oct)	Pfizer, Groton, CT	<i>A lifetime in drug metabolism & disposition: My top ten moments of inspiration, consternation, and duh!</i>
2019		
2019 (Apr)	Boehringer Ingelheim, Ridgeway, CT	<i>A lifetime in drug metabolism & disposition: My top ten moments of inspiration and consternation</i>
2019 (Jun)	21 st International Conference on Cytochrome P450. University of Queensland, Brisbane Australia	<i>In vitro studies of drug clearance and drug interactions My top-ten list of honest mistakes in experimental design and interpretation</i>

Year	Institution or meeting	Title of presentation
2019 (Sep)	22 nd Annual Land O' Lakes Conference on Drug Metabolism Applied Pharmacokinetics, University of Wisconsin, Madison, Wisconsin	<i>Regulatory Guidance for In Vitro Drug Interactions: FDA versus EMA versus PMDA</i> Not presented due to illness
2020		
2020 (Mar)	Annual Society of Toxicology conference in Anaheim, California. The meeting was canceled due to the Covid-19 pandemic. On April 3 rd , I chaired a virtual meeting to present Continuing Education Course AM07.	<i>AM07: The basics of in vitro xenobiotic metabolism and drug-drug interaction investigations: Applicability to all xenobiotics</i>
2020 (May)	DDI 2018 – The 10 th International Workshop, Marbach Castle, Germany, The meeting was canceled due to the Covid-19 pandemic.	<i>Metabolic reaction phenotyping: Do's and Don'ts, and the Oscar Nomination Process (is metabolism the Best Actor or the Best Supporting Actor?)</i>
2021		
2021 (May)	DDI 2021 – The 10 th International Workshop, Marbach Castle, Germany. Virtual meeting.	<i>What did the FDA change when it finalized its in vitro drug-drug interaction guidance in January, 2020?</i>
2021 (June)	DDI 2021 – The 10 th International Workshop, Marbach Castle, Germany. Virtual meeting	<i>Metabolic reaction phenotyping: Do's and Don'ts, and the Oscar-nomination process (is metabolism the best actor or the best supporting actor?)</i>

RESEARCH GRANTS

No	Funding source, dates & amount	Title, role and percent effort
1	Biomedical Research Support Grant Kansas University Medical Center Awarded 1983-1984 Direct costs: \$15,000	<i>Multiple forms of cytochrome P-450</i>
2	Biomedical Research Support Grant Kansas University Medical Center Awarded 1984 Direct costs: \$26,000	<i>Shared instrumentation-Spectrophotometer</i>
3	Speas Foundation Grant for Cancer Research Awarded 1984-1985 Direct costs: \$25,000	<i>Cytochrome P450 in chemical carcinogenesis</i>
4	Pharmaceutical Manufacturers Association Awarded 1985-1986 Direct costs: \$7,750	<i>Pharmacology and toxicology of rat cytochrome P-450-PCN</i>
5	National Institutes of Health. ES03765 (years 1-3) From March 1, 1985, to February 28, 1988 Direct costs: \$75,580 per year for 3 years	<i>Biochemical toxicology of cytochrome P450</i> Percent Effort: 40% (principal investigator)
6	Department of Defense. USA DAMD 17-86-G-6038 From September 1, 1986, to August 31, 1988 Direct costs: \$42,000 per year for 2 years	<i>Program of basic research on neurotoxins</i> Percent effort: 5% (co-investigator, 1 of 12)
7	Biomedical Research Support Grant Kansas University Medical Center Awarded 1989 Direct costs: \$13,000	<i>Shared Instrumentation – Densitometer</i>
8	National Institutes of Health. ES00166 Research Career Development Award From July 1, 1986, to June 30, 1991 Direct costs: \$46,586 per year for 5 years	<i>Biochemical toxicology of cytochrome P-450</i>
9	Wesley Foundation Postdoctoral training grant From June 15, 1989 to June 14, 1991 Direct costs: \$36,000 per year for 2 years	<i>Purification of carcinogen-metabolizing enzymes</i>
10	Biomedical Research Support Grant Kansas University Medical Center Awarded 1991 Direct costs: \$19,000	<i>Shared Instrumentation - Radioactivity detector</i>
11	National Institutes of Health. GM37044 (years 1-5) From March 1, 1988, to February 28, 1993 Direct costs: \$56,578 per year for 5 years	<i>Catatotoxic steroids: Mechanism of action</i> Percent effort: 35% (principal investigator)
12	National Institutes of Health. ES03765 (years 4-8)	<i>Biochemical toxicology of cytochrome P450</i>

No	Funding source, dates & amount	Title, role and percent effort
	From April 1, 1989 to March 31, 1994 Direct costs: \$91,133 per year for 5 years	Percent effort: 25% (principal investigator)
13	National Institutes of Health. ES04996 (years 1-4) From July 1, 1989 to June 30, 1993 Direct costs: \$78,152 per year for 4 years (with one-year, no-cost extension)	<i>Biochemical toxicology of carboxylesterases</i> Percent effort: 25% (principal investigator)
14	Procter & Gamble Company - University Animal alternatives Research Program From January 1, 1992 to December 31, 1994 Direct costs: \$44,490 per year for 3 years	<i>Induction of human liver P450 enzymes in vitro</i> Principal Investigator
15	Pfizer From September 1, 1995 to August 31, 1996 Direct costs: \$ \$50,184 per year for 1 year	<i>Induction of human P450 enzymes</i> Principal Investigator
16	National Institutes of Health. GM37044 (years 6-10). From February 1, 1993, to January 31, 1997 (with one-year, no-cost extension) Direct costs: \$93,851 per year for 4 years	<i>Catatoxic steroids: Mechanism of action</i> Percent effort: 25% (principal investigator)
17	National Institutes of Health. Competitive renewal of ES03765 (years 9-12) From Dec 1, 1994 to Nov 30, 1998 (with one-year, no-cost extension to Nov 30, 1999) Direct costs: ~\$145,370 per year for 4 years	<i>Biochemical toxicology of cytochrome P-450</i> Percent effort: 20% (principal investigator)

Exhibit 18

Defendants' Experts CVs

**CURRICULUM VITAE
OREGON HEALTH & SCIENCE UNIVERSITY**

NAME **Jonathan Emens, M.D.**

DATE **07/19/2021**

PRESENT POSITION AND ADDRESS

Academic Rank: **Associate Professor**

Department/Division: **Psychiatry, Medicine**

Professional Address: **VA Portland Health Care System, 3710 SW U.S. Veterans Hospital Rd., P3-MHADM, Portland, OR 97239**

E-Mail Address:

I. EDUCATION

Undergraduate and Graduate:

05/25/92, B.A., Oberlin College

06/07/98, M.D., University of Massachusetts Medical School

Postgraduate:

1998-2002, Internship and Residency, Oregon Health & Science University

Certification:

American Board of Psychiatry and Neurology, 53313, 1/2004, 2/2014

American Board of Sleep Medicine, 2676, 3/22/2005

Licenses:

Oregon, 1/1/06, Active, MD23635, 12/31/21

II. PROFESSIONAL EXPERIENCE

Academic:

07/2002-07/2014, Assistant Professor, Department of Psychiatry, OHSU

07/2014-Present, Associate Professor, Department of Psychiatry, OHSU

10/2013-Present, Assistant Professor, Department of Medicine, OHSU

10/2013-11/2019, Staff Physician, Division of Hospital & Specialty Medicine, VA Portland Health Care System

11/2016-Present, Affiliate Faculty, Oregon Institute of Occupational Health Sciences

Administrative:

07/2014-07/2016, Acting Director, Portland VA Medical Center Sleep Laboratory and Clinic

07/2016-06/2018, Program Director, OHSU Sleep Medicine Fellowship

07/2018-06/2020, Associate Program Director, OHSU Sleep Medicine Fellowship

11/2019-Present, Deputy Clinical Director, Mental Health & Clinical Neurosciences Division, VA Portland Health Care System

Other:

1992-1994, Research Assistant, Section on Sleep Disorders and Circadian Medicine, Division of Endocrinology, Department of Medicine, Harvard Medical School and Brigham and Women's Hospital

III. SCHOLARSHIP

Area(s) of Research/Scholarly Interest:

Chronobiology of Mood Disorders, Circadian Physiology and Sleep Disorders

Grants and Contracts:

Current Support

1R01HL140577 09/15/2017 – 05/31/2022

National Heart, Lung, and Blood Institute (NHLBI)

Circadian mechanisms of cardiovascular risk in obesity

Role: co-Principal Investigator (Steven Shea, Ph.D., P.I. until 6/1/2021)

15% Effort

1R01HL142064 04/10/2018 – 03/31/2022

National Heart, Lung, and Blood Institute (NHLBI)

Sleep and Circadian Mechanisms Contributing to Disparity in Prevalence of Hypertension between Black and White Americans

Role: co-Investigator, Steven Shea, Ph.D. (P.I.)

5% Effort

Prior Support

1R01HL125893 07/01/2015 – 06/30/2020

National Heart, Lung, and Blood Institute (NHLBI)

Circadian rhythms and cardiovascular risk

Role: co-Investigator, Steven Shea, Ph.D. (P.I.)

10% Effort

K23 RR017636 03/01/2003 - 02/28/2010

National Institutes of Health, NCRR
Genetics of Morning/Evening Types in the Blind/Sighted
Role: P.I.
80% Effort

5R01EY018312 06/25/1997 - 02/29/2012
National Eye Institute, NEI
Melatonin for Circadian Sleep Disorders in the Blind
Role: co-Investigator, Alfred Lewy (P.I.)

2006 J. Christian Gillin, M.D. Research Award 02/01/2007 - 07/31/2008
Sleep Research Society Foundation
Determination of Intrinsic Circadian Period in Blind Individuals with Non-Entrained Circadian
Rhythm Sleep Disorders.
Role: P.I.

NARSAD Young Investigator Award 07/01/2003 - 06/30/2008
Evaluation and Treatment of Circadian Misalignment in Non-seasonal Major Depression
(National Alliance for Research on Schizophrenia and Depression)
Role: P.I.

Investigator Initiated Trial 01/01/2009 – 12/31/2011
Forest Research Institute
The Circadian Effects of Escitalopram
Role: P.I.

Neuropsychiatric Institute (NPI) 07/01/2009 – 06/30/2011
Circadian Misalignment in ADHD
Role: P.I.

Publications/Creative Work:

Peer-reviewed

Czeisler CA, Shanahan TS, Klerman EB, Martens H, Brotman DJ, **Emens JS**, Klein T, Rizzo JF. Suppression of Melatonin Secretion in Some Blind Patients by Exposure to Bright Light. *New England Journal of Medicine* 1995; 332: 6-11. PMID: 7990870

Czeisler CA, Duffy JF, Shanahan TL, Brown EN, Mitchell JF, Rimmer DW, Ronda JM, Silva EJ, Allan JS, **Emens JS**, Dijk DJ, Kronauer RE. Stability, Precision, and Near-24-Hour Period of the Human Circadian Pacemaker. *Science* 1999; 284: 2177-81. PMID: 10381883

Lewy AJ, Hasler BP, **Emens JS**, Sack RL. Pretreatment Circadian Period in Free Running Blind People May Predict the Phase Angle of Entrainment to Melatonin. *Neuroscience Letters* 2001; 313: 158-60. PMID: 11682151

Lewy AJ, **Emens JS**, Sack RL, Hasler BP, Bernert RA. Low, but not high doses of melatonin entrained a free-running blind person with a long circadian period. *Chronobiology International* 2002; 19: 649-658. PMID: 12069043

Klerman EB, Shanahan TL, Brotman DJ, Rimmer D, **Emens JS**, Rizzo JF, Czeisler CA. Photic Resetting of the Human Circadian Pacemaker in the Absence of Conscious Vision. *Journal of Biological Rhythms* 2002, 17: 548-555. PMID: 12465888

Lewy AJ, **Emens JS**, Sack RL, Hasler BP, Bernert RA. Zeitgeber Hierarchy in Humans: Resetting the Circadian Phase Positions of Blind People Using Melatonin. *Chronobiology International* 2003; 20: 837-852. PMID: 14535357

Lewy AJ, **Emens JS**, Bernert RA, Lefler BJ. Eventual Entrainment of the Human Circadian Pacemaker by Melatonin is Independent of the Circadian Phase of Treatment Initiation: Clinical Implications. *Journal of Biological Rhythms* 2004; 19: 68-75. PMID: 14964705

Emens JS, Lewy AJ, Lefler BJ, Sack RL. Relative Coordination to Unknown “Weak Zeitgebers” in Free-Running Blind Individuals. *Journal of Biological Rhythms* 2005, 20: 159-167. PMID: 15834112

Lewy AJ, **Emens JS**, Lefler BJ, Yuhas K, Jackman AR. Melatonin Entrainment of Free-Running Blind People According to a Physiological Dose-Response Curve. *Chronobiology International* 2005, 22: 1093-1106. PMID: 16393710

Lewy AJ, Lefler BJ, **Emens JS**, Bauer VK. The circadian basis of winter depression. *Proceedings of the National Academy of Science USA* 2006; 103:7414-7419. PMID: 16648247

Emens JS, Yuhas K, Rough J, Kochar N, Peters D, Lewy AJ. Phase Angle of Entrainment in Morning- and Evening-Types under Naturalistic Conditions. *Chronobiology International* 2009; 26: 474-493. PMID: 19360491

Emens JS, Lewy AJ, Kinzie JM, Arntz D, Rough J. Circadian Misalignment in Major Depressive Disorder. *Psychiatry Research* 2009; 168: 259-261. PMID:19524304

Lewy AJ, **Emens JS**, Songer JB, Sims N, Laurie AL, Fiala SC. Winter Depression: Integrating Mood, Circadian Rhythms, and the Sleep/Wake and Light/Dark Cycles into a Bio-Pscho-Social-Environmental Model. *Sleep Medicine Clinics* 2009;4(2):285-99. PMID:20160896

Emens JS, Lewy AJ, Laurie AL, Songer JB. The Rest/Activity Cycle and the Melatonin Rhythm in Blind Free-runners Have Similar Periods. *Journal of Biological Rhythms* 2010; 25: 381-384. PMID: 20876818

Emens JS, Laurie AL, Songer JB, Lewy AJ. Non-24-Hour Disorder in Blind Individuals Revisited: Variability and the Influence of Environmental Time Cues. *Sleep* 2013; 36: 1091-1100. PMID: 23814347

Emens JS and Burgess HJ. Effect of Light and Melatonin and Other Melatonin Receptor Agonists on Human Circadian Physiology. *Sleep Medicine Clinics* 2015;10: 435-453. PMID: 26568121

Auger RR, Burgess HJ, **Emens JS**, Deriy LV, Thomas SM, Sharkey KM. Clinical Practice Guideline for the Treatment of Intrinsic Circadian Rhythm Sleep-Wake Disorders: Advanced Sleep-Wake Phase Disorder (ASWPD), Delayed Sleep-Wake Phase Disorder (DSWPD), Non-24-Hour Sleep-Wake Rhythm Disorder (N24SWD), and Irregular Sleep-Wake Rhythm Disorder (ISWRD). An Update for 2015. *Journal of Clinical Sleep Medicine* 2015; 11: 1199-1236. PMID: 26414986

Burgess HJ and **Emens JS**. Circadian-Based Therapies for Circadian Rhythm Sleep-Wake Disorders. *Current Sleep Medicine Reports* 2016; 2: 158-165. PMID: 27990327

Emens JS and Eastman CI. Diagnosis and Treatment of Non-24-h Sleep–Wake Disorder in the Blind. *Drugs* 2017; 77: 637-650. PMID: 28229310

Bordley J, Agustin AG, Ahmed MA, Khalid R, Paluso AM, Kobza BS, Spaugy AW, **Emens J**, Desai SS, Khan A. Restoration of resident sleep and wellness with block scheduling. *Medical Education* 2017; 51: 1241-1249. PMID: 28971499

Burgess HJ and **Emens JS**. Drugs Used in Circadian Sleep-Wake Rhythm Disturbances. *Sleep Medicine Clinics* 2018; 13:231-241. PMID: 29759273.

Thosar SS, Herzig MX, Roberts SA, Berman AM, Clemons NA, McHill AW, Bowles NP, Morimoto M, Butler MP, **Emens JS**, Shea SA. Lowest perceived exertion in the late morning due to effects of the endogenous circadian system. *British Journal of Sports Medicine* 2018; 52: 1011-1012. PMID: 29475839

Thosar SS, Rueda JF, Berman AM, Lasarev MR, Herzig MX, Clemons NA, Roberts SA, Bowles NP, **Emens JS**, Ellison DH, Shea SA. Separate and interacting effects of the endogenous circadian system and behaviors on plasma aldosterone in humans. *American Journal of Physiology-Regulatory, Integrative and Comparative Physiology* 2019; 316:R157-R164 PMID: 30521366

Thosar SS, Berman AM, Herzig MX, McHill AW, Bowles NP, Swanson CM, Clemons NA, Butler MP, Clemons AA, **Emens JS**, Shea SA. Circadian Rhythm of Vascular Function in

Midlife Adults. *Arteriosclerosis, Thrombosis & Vascular Biology* 2019; 39:1203-1211 PMID: 31070470

Emens JS, Berman AM, Thosar SS, Butler MP, Roberts SA, Clemons NA, Herzig MX, McHill AW, Morimoto M, Bowles NP, Shea SA. Circadian Rhythm in Negative Affect: Implications for Mood Disorders. *Psychiatry Research* 2020; 293: 1-4 PMID: 32777620

Duffy JF, Saba M, Abbott SM, Burgess HJ, Crowley SJ, **Emens JS**, Lawrence J, Epstein LJ, Gamble KL, Hasler BP, Kristo DA, Malkani RG, Rahman SA, Thomas, SJ, Wyatt JK, Zee PC, Klerman EB. Workshop report. Circadian rhythm sleep–wake disorders: gaps and opportunities. *Sleep* 2021; 44:1-15 PMID: 33582815

Emens JS, St Hilaire MA, Klerman EB, Brotman DJ, Lin AL, Lewy AJ, Czeisler CA. Behaviorally and environmentally induced non-24-hour sleep-wake rhythm disorder in sighted patients. *Journal of Clinical Sleep Medicine* 2021; In Press PMID: 34402783

Book Chapters

Emens JS, Lewy AJ. Sleep and Circadian Rhythms in the Blind. In: *Neuroendocrine Correlates of Sleep/Wakefulness*. New York, NY: Springer, 2006: 311-323.

Lewy AJ, **Emens JS**, Songer J, Rough J. The Neurohormone Melatonin as a Marker, Medicament and Mediator. In: Pfaff DW, Arnold AP, Etgen AM, Fahrbach SE, Rubin RT, eds. *Hormones, Brain and Behavior*. San Diego: Academic Press; 2009: 2505-26.

Emens JS. Non-24-Hour Sleep-Wake Rhythm Disorder. In: Auger, R.R., editor. *Circadian Rhythm Sleep-Wake Disorders*. New York, NY: Springer, 2020: 123-136.

Emens JS, Super ER, Sanford JN. Circadian Sleep Disorders. In: Gozal, D, Kheirandish-Gozal, L, eds. *Pediatric Sleep Medicine*. Cham, Switzerland: Springer Nature, 2021: 403-413.

Editorials

Emens JS. Circadian Rhythms: The Price of Electric Light. *Current Biology* 2017;27:R144-R145.

Abstracts

Emens JS, Brotman DJ, Czeisler CA. Evaluation of the Intrinsic Period of the Circadian Pacemaker in a Patient with a non-24-hour Sleep-Wake Schedule Disorder. *Sleep Research* 1994; 23:256.

Shanahan TL, **Emens JS**, Czeisler CA. Estimation of the Intrinsic Period of the Human Circadian Pacemaker During Forced Desynchrony using the Daily Melatonin Pattern. *Sleep Research* 1994; 23:511.

Emens J, Lewy A, Bernert R, Lefler B. Entrainment of the Human Circadian Pacemaker by Melatonin is Independent of the Circadian Phase of Treatment Initiation. *Chronobiology International* 2003; 20: 1189-1191.

Lewy AJ, Lefler BJ, Hasler BP, Bauer VK, Bernert RA, **Emens JS** (2003) Plasma DLMO₁₀ zeitgeber time 14: The therapeutic window for phase-delayed winter depressives treated with melatonin. *Chronobiology International* (2003); 20: 1215-1217.

Lewy AJ, **Emens J**, Lefler BJ, Koenig AR, Yuhas K, Johnson KP, Giger PT. Melatonin-Induced Phase Delays of the Human Circadian Pacemaker. *Sleep* 2004; 27: A79.

Emens JS, Lewy AJ, Lefler BJ, Yuhas K, Koenig AR, Johnson, KP, Giger, PT. Relative Coordination to Unknown Weak Zeitgebers Influences Lowest Entraining Dose of Exogenous Melatonin. *Sleep* 2005; 28: A69.

Emens JS, Lewy AJ, Lefler BJ, Yuhas K, Jackman AR, Johnson, KP. Melatonin Entrainment Free-Running Blind Individuals with Circadian Periods Less Than 24 Hours. *Sleep* 2006; 29: A62.

Emens JS, Lewy AJ, Yuhas K. Women Have a Longer Phase Angle of Entrainment than Men. *Sleep* 2007; 30: A63.

Emens JS, Rough J, Yuhas K, Songer J, Lewy AJ. Free-running, but not entrained, blind individuals have the same period under forced-desynchrony as in the field. *Sleep* 2008; 31: A47-48.

Emens JS, Rough J, Arntz D, Lewy AJ. Circadian Misalignment Correlates with Symptom Severity in Non-Seasonal Depression. *Sleep* 2008; 31: A314.

Emens JS, Laurie AL, Songer JB, Lewy AJ. The non-24 hour period of the rest/activity cycle is identical to that of the free-running melatonin rhythm in blind and sighted individuals. *Sleep* 2009; 32: A45.

Emens JS, Lewy AJ, Rough JN, Songer JB. Sub-Clinical Dysphoria Correlates with Phase-Delayed Circadian Misalignment in Healthy Individuals. *Sleep* 2009; 32: A355-356

Emens JS, Laurie AL, Lewy AJ. Blind Free-Runners can Spontaneously Entrain to Unknown Zeitgebers for up to 345 Consecutive Days. *Sleep* 2011; 34: A165.

Emens JS, Laurie AL, Lewy AJ. Circadian Misalignment in Major Depression. *Sleep* 2012; 35: A325.

Emens JS, Lewy AJ. Intra-Individual Variability in Circadian Phase. *Sleep* 2012; 35: A65.

Emens JS, Lewy AJ. Short Sleep Durations Correlate with Body Mass Index in Evening Types but not in Morning Types. *Sleep* 2013; 36: A49.

Emens JS, Berman AM, Thosar SS, Butler MP, Roberts SA, Clemons NA, Herzig MX, Morimoto M, Bowles NP, McHill AW, Shea SA. Positive and Negative Affect Both Contribute to the Endogenous Circadian Rhythm in Mood. *Sleep* 2017; 40: A68.

Bowles NP, McHill AW, Thosar SS, Herzig MX, Clemons NA, Roberts SA, Berman AM, Morimoto M, Butler MP, **Emens JS**, Shea SA. The Increase in Hunger Across a Sleep and Fasting Period is Modulated by the Circadian System. *Sleep* 2017; 40:A72.

Thosar SS, Herzig MX, Berman AM, Roberts SA, Clemons NA, Morimoto M, Burchill LJ, Butler MP, **Emens JS**, McHill AW, Bowles NP, Shea SA. Endogenous Circadian Rhythm in a Marker of Myocardial Oxygen Consumption. *Sleep* 2017; 40:A252.

Emens JS, Berman AM, Butler MP, Thosar SS, Roberts SA, Clemons NA, Herzig MX, Morimoto M, Bowles NP, McHill AW, Shea SA. Endogenous Circadian Rhythm of Mood is Diminished in Sleep Apnea. *Sleep* 2018; 41: A21.

McHill AW, Thosar SS, Bowles NP, Berman AM, Herzig MX, Clemons NA, Morimoto M, Butler MP, **Emens JS**, Purnell JQ, Shea SA. The Influence of Obesity and Circadian Timing on Human Glucose Regulation. *Sleep* 2018; 41: A17

Thosar SS, Butler MP, Bowles NP, McHill AW, Berman AM, Herzig MX, Stewart AV, Roberts SA, Clemons NA, Morimoto M, **Emens JS**, Shea SA. The Circadian System Modulates Cardiovascular Responses to Standing Differently in People with Obstructive Sleep Apnea Compared to Healthy Controls. *Sleep* 2019; 42: A18

Ordaz-Johnson O, McHill AW, Thosar SS, Bowles NP, Berman AM, Herzig MX, Clemons NA, Morimoto M, Butler MP, **Emens JS**, Shea SA. Circadian Regulation of Hunger is Similar in Lean and Non-lean Individuals. *Sleep* 2019; 42: A19-20

Bowles NP, Thosar SS, Herzig MX, Clemons NA, Sauber G, Roberts SA, Berman AM, Morimoto M, Stewart AV, McHill AW, Butler MP, **Emens JS**, Hillard CJ, Shea SA. Altered Endogenous Circadian Rhythm of the Endocannabinoid Anandamide by Body Mass Index. *Sleep* 2019; 42: A21

McHill AW, Thosar SS, Bowles NP, **Emens JS**, Purnell JQ, Gillingham M, Shea SA. Resting Metabolism and the Metabolic Response to Exercise Follow Circadian Patterns with Day/Night

Differences in Substrate Utilization Between Lean and Obese Adults. Sleep 2020; 43: A14

Stubbers KM, Thosar SS, Butler MP, Bowles NP, McHill AW, Berman AM, Herzig MX, Roberts SA, Clemons NA, Morimoto M, Shea SA, **Emens JS**. Apnea-Hypopnea Index is Positively Correlated with Mood Disturbance. Sleep 2020; 43: A218-219

Invited Lectures, Conference Presentations or Professorships:

International and National

"Evaluation of the Intrinsic Period of the Circadian Pacemaker in a Patient with a non-24-hour Sleep-Wake Schedule Disorder." Presented at the annual meeting of the Association of Professional Sleep Societies, Boston, MA, June 1994.

"Relative Coordination to Unknown Weak Zeitgebers Influences Lowest Entraining Dose of Exogenous Melatonin." Presented at the annual meeting of the Associated Professional Sleep Societies, Denver, CO, June 2005.

"Circadian Rhythm Sleep Disorders in the Blind." Division of Sleep Medicine Grand Rounds, Department of Medicine, Harvard Medical School and Brigham and Women's Hospital, Boston, MA, October 17, 2005.

"Melatonin Entrain Free-Running Blind Individuals with Circadian Periods Less Than 24 Hours." Presented at the biannual meeting of the Society for Research on Biological Rhythms, Sandestin, FL, May 2006.

"Circadian Rhythm Sleep Disorders in the Blind: Impact of Relative Coordination on Diagnosis and Treatment." Presented at the annual meeting of the Associated Professional Sleep Societies, Salt Lake City, UT, June 2006.

"Melatonin Entrain Free-Running Blind Individuals with Circadian Periods Less Than 24 Hours." Presented at the annual meeting of the Associated Professional Sleep Societies, Salt Lake City, UT, June 2006.

"Impact of Environmental Time Cues on Circadian Rhythms in the Blind." Presented at the annual Winter Conference on Brain Research, Snowmass, CO, February 2007.

"Circadian Misalignment Correlates with Symptom Severity in Non-Seasonal Depression." Presented at the annual meeting of the Associated Professional Sleep Societies, Baltimore, MD, June 2008.

"Morning- and Evening-Types have Different Phase Angles of Entrainment to Light under Naturalistic Condition." Presented at the annual meeting of the Associated Professional Sleep Societies, Baltimore, MD, June 2008.

“Human Models to Test the Effect of Melatonin and Melatonin Ligands on Circadian Dysfunction.” Presented at the Federation of American Societies for Experimental Biology (FASEB) Summer Research Conference (Melatonin Receptors: Actions and Therapeutics), Snowmass, CO, August 2008.

“The non-24 hour period of the rest/activity cycle is identical to that of the free-running melatonin rhythm in blind and sighted individuals.” Presented at the annual meeting of the Associated Professional Sleep Societies, Seattle, WA, June 2009.

“Impact of Circadian Misalignment on Mood.” Presented at the annual meeting of the Associated Professional Sleep Societies, Seattle, WA, June 2009.

“Resetting Circadian Rhythms with Melatonin in Blind Individuals.” Presented at the annual meeting of the Associated Professional Sleep Societies, Minneapolis, MN, June 2011.

“Circadian Misalignment in Mood Disorders.” Presented at the annual meeting of the Associated Professional Sleep Societies, Minneapolis, MN, June 2011.

“Intra-Individual Variability in Circadian Phase.” Presented at the annual meeting of the Associated Professional Sleep Societies, Boston, MA, June 2012.

“Circadian Misalignment in Mood Disorders: Challenges in Evidence-Based Medicine.” Presented at the annual meeting of the Associated Professional Sleep Societies, Seattle, WA, June 2015.

“Introduction to Circadian Physiology and Circadian Rhythm Sleep Disorders (CRSDs).” Presented at the annual meeting of the Associated Professional Sleep Societies, Denver, CO June 2016.

“Non-24-Hour Sleep-Wake Rhythm Disorder (N24SWD).” Presented at the annual meeting of the Associated Professional Sleep Societies, Denver, CO June 2016.

“Insomnia: Diagnosis and Treatment.” Presented to the National Veterans Administration Mental Illness Research, Education and Clinical Center (MIRECC), March 2021

Regional and Local

“Melatonin treatment of winter depression and other circadian phase disorders.” Presented at the annual meeting of the West Coast College of Biological Psychiatry, Long Beach, CA, April 2001.

“Circadian Sleep Disorders.” Presented at the biennial meeting of the Pacific Northwest Sleep Association, Stevenson, WA, March 2009.

“Sleep Disorders and Insomnia.” Oregon Psychiatric Association, Portland, OR, March 6, 2010.

“Psychiatric Implications of Circadian Misalignment.” OHSU Department of Psychiatry Grand Rounds, Portland, OR, November 2, 2010

"Medications and Sleep." Presented at the biennial meeting of the Pacific Northwest Sleep Association, Stevenson, WA, March 2011.

“Nightmares.” Oregon Psychiatric Physicians Association, Ashland, OR, September 19, 2014.

“Insomnia.” Oregon Psychiatric Physicians Association, Ashland, OR, September 20, 2014.

“Sleep Deprivation.” OHSU Cardiothoracic Surgery Grant Rounds, Portland, OR, February 26, 2018.

“Circadian Rhythm in Negative Affect: Implications for Mood Disorder.” OHSU Department of Psychiatry Grand Rounds, Portland, OR, March 2, 2021

IV. SERVICE

Membership in Professional Societies:

American Psychiatric Association, Distinguished Fellow (DFAPA)

Oregon Psychiatric Physicians Association

American Academy of Sleep Medicine, Fellow (FAASM)

Sleep Research Society

Granting Agency Review Work:

Canadian Institutes of Health Research (CIHR), 2/23/10, ad-hoc peer review committee member

Editorial and Ad Hoc Review Activities:

Editorial Reviewer for the Archives of General Psychiatry, Psychiatry Research, Journal of Psychiatric Research, Psychopharmacology, Journal of Affective Disorders, Sleep, Sleep Medicine, Journal of Biological Rhythms, PloS ONE, PloS Medicine, Current Biology, Journal of Circadian Rhythms, Early Human Development, and Nature and Science of Sleep.

Committees:

International/National

American Academy of Sleep Medicine (AASM) Task Force on Circadian Rhythm Sleep Disorders (CRSDs), 6/2012-9/2015

The task force performed a systematic review of the literature, conducted a PICO question based rating of all manuscripts, and did an extensive extraction of data from the original manuscripts. The task force conducted a meta-analysis of the data and wrote a manuscript that was published in the *Journal of Clinical Sleep Medicine* that summarized

the findings and presented current AASM guidelines for the treatment of Circadian Rhythm Sleep Disorders.

United States Food and Drug Administration (FDA), Special Government Employee (SGE) Consultant, Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC), 1/12/15.

The committee reviewed and discussed safety and efficacy data relevant to the new drug application (NDA) of desmopressin (proposed trade name Nocurna) for the treatment of nocturia due to nocturnal polyuria in adults.

Sleep Research Society Circadian Rhythms Sleep Disorders Workshop, 6/8/19, San Antonio, TX
Group leader, Circadian Abnormalities in Other Medical Conditions

Aims of the workshop were to outline what is the current state of the science for each disorder, describe the adequacy of existing diagnosis and treatment guidelines for the disorder, and identify knowledge gaps related to the pathophysiology, diagnosis, and/or treatment.

United States Food and Drug Administration (FDA), Special Government Employee (SGE) Temporary Member, Pharmacy Compounding Advisory Committee Meeting (PCAC), 6/9/21.

The committee reviewed and discussed the inclusion of melatonin on the list of bulk drug substances under section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Departmental

Department of Psychiatry Promotion and Tenure committee, 2001-2002

Department of Psychiatry Promotion and Tenure committee, 2008-2010

Community Service:

All School Presentation on Sleep Science and Sleep Health, 2/20/04

The Northwest Academy, Portland, OR, Grades 6-12, 2/20/04

TIES Clinical Lab Observation, 2006

GCRC and OHSU hosted middle school science teachers in a summer program designed to introduce them to clinical research. Emily Robins and Lorrie Bell, Reynolds Middle School, Fairview, OR.

TIES Clinical Lab Observation, 2007

CTRC and OHSU hosted middle school science teachers in a program designed to introduce them to clinical research. Brad Agenbroad and Helen Peynado, French Prairie Middle School, Woodburn, OR.

Body Worlds Lecture Series, 8/21/07, "Changing the World, One Adult at a Time: Sleep Health"

Class Presentation on Sleep Science and Sleep Health, 11/14/08

Atkinson Elementary School, Portland, OR, Ms. Cindy Dulcich, 4th/5th grade class
Comments from Ms. Dulcich: "I thought he was absolutely wonderful with the kids. He truly was one of the best speakers I've ever had...knowledgeable, affable and very cognizant of how to get and keep the attention of 10 year olds!"

National Sleep Foundation (NSF) Non-24-Hour Sleep Wake Disorder expert review panel member, 2014

Provided input to the NSF website on Non-24 Hour Sleep Wake Disorder that provides information on symptoms, diagnosis, treatment, and resources for this circadian rhythm sleep disorder.

National Sleep Foundation (NSF) Bright Schools Contest Expert Review Panel member, 2014-2017

I assisted in the development of guidelines and resource materials for an NSF contest for middle school students. The goal of the contest is to create a learning program that teaches students about the connection between light & sleep and student health & performance.

Clinical Responsibilities (since last promotion):

Portland VA Medical Center Sleep Clinic

One to four half-day clinics per week: evaluation and treatment of Veterans with a variety of sleep disorders including sleep apnea (obstructive and central), insomnia (primary and secondary), movement disorders (restless legs syndrome and periodic limb movement disorder), parasomnias (slow-wave sleep parasomnias and REM behavior disorder), and narcolepsy. Currently one clinic per month is a telemedicine clinic with Bend and The Dalles, OR (begun August, 2013).

Interpretation of Polysomnography Studies including diagnostic and treatment studies (CPAP, BiPAP, BiPAP ASV, BiPAP AVAPS, and NOX-T3 portable studies)

Supervision of sleep medicine fellows (see below)

Supervision of CPAP technician (DME) clinic

Triaging of sleep medicine consults (~50-100 per week)

Adult Psychiatry, Portland VA Medical Center Mental Health

Group Therapy Facilitator: Cognitive Behavioral Therapy for Insomnia (CBT-I), weekly group therapy for Veterans, co-facilitator

V. TEACHING (OHSU Educator's Portfolio):

Overview of Role as an Educator:

I have worked as an educator in both a clinical and research context for medical students, psychiatry residents, sleep medicine fellows, and geriatric psychiatry fellows:

Current Educator Roles:

1. One to two half days per week clinical supervision of Sleep Medicine Fellows in the Portland VA Medical Center Sleep Clinic during their one year fellowship:

2012-2013, Conor Sheehy, M.D. and Nimesh Patel, M.D.

2013-2014, Justin Hale, M.D. and Akhil Raghuram, M.D.

2014-2015, Andrea Matsumura, M.D. and Robert Weir, MB BS, MRCOphth

2015-2016, Tanvi Mukundan, M.D.

2016-2017, Jillian Sanford, M.D. and Michael Fall, M.D.

2017-2018, Tara Rachakonda, M.D. and Stephen Yau, M.D.

2018-2019, Stanley Thomas, D.O.

2019-2020, Valerie Ing, D.O. and Samir Majmudar, D.O.

2020-2021, Raeesa Khalid, M.D. and Caroline Ing, M.D.

2021-Present, Anum Choudhry, M.D. and Kelvin Monroe, M.D.

2. Lectures:

Sleep Medicine Fellows :

“Introduction to Sleep Apnea”, yearly

“Introduction to Insomnia”, yearly

“Chronobiologic Mechanisms/Circadian Rhythm Disorders”, yearly

“Endocrine Physiology In Sleep Medicine”, yearly

“Narcolepsy and Hypersomnias”, yearly

“Sleep and Psychiatric Disorders (excluding PTSD)”, yearly

“Opiates and Sleep Disordered Breathing”, yearly

“PTSD and Sleep”, yearly

“Sleep and Aging”, yearly

Journal Club/case presentations, five per year in the Sleep Medicine Clinic

Psychiatry residents:

“Insomnia” PGY-I, twice per year, most recently 1/26/21

“Sleep Physiology” PGY-III, once per year, most recently 9/10/19

Geriatric Medicine Fellows

Sleep Apnea and Insomnia, yearly, most recently 9/22/20

Prior Educator Roles:

1. OHSU Sleep Medicine Fellowship Associate Program Director, 7/2016-6/2020

I took over as Program Director beginning with the 2016-2017 academic year and currently serve as the Associate Program Director. I was responsible for all aspects of fellowship training including orientation, scheduling, didactics & case conference planning, mentorship, fellow evaluations, and recruitment.

2. Half day per week clinical supervision of Sleep Medicine Fellows in the OHSU Sleep Disorders Medicine Clinic during their one year fellowship:

2007-2008, Praseeda Sridharan, M.D.

2010-2011, Vanessa Peterson, M.D. and Oleg Kouskov, M.D.

2011-2012, Nuripam Singh, M.D. and Ramona Ionita, M.D.

3. Clinical supervision of Geriatric Psychiatry Fellows (Half to full day per week).

Willow Naimark, M.D. 10/2009 - 12/2009

Chris Logan, M.D. 1/2010 - 4/2010

Jeanette Ardans, M.D. 7/2010 - 9/2010

Vanessa McDonald, M.D. 12/2010 - 2/2011

Katherine Tacker, M.D. 5/2011 - 8/2011

Michael Yao, M.D., 3/2013

Clara Ruiz, M.D., 8/2013-1/2014

Mary LaJoy, M.D., 8/2014-2/2015

John Wilson, M.D., 3/2015-6/2015

Dan Nguyen, M.D., 5/2015-7/2015

JJ Schumacher, M.D., 3/2016- 7/2016

Julie Cohn, M.D., 8/2017-9/2017

4. Clinical supervision of MS-III student in the Sleep Disorders Medicine Subspecialty elective during the 5 week psychiatry clerkship (Half day clinic per week),.

Partial list of students supervised: 7/04-8/04, Targol Saedi; 8/04-9/04, Mylynda Massart; 9/04-10/04, Kristopher Spinning; 1/05-2/05, Hon Ho; 2/05-3/05, David Carne; 3/05-4/05, Julie Craig; 4/05-5/05, Amy Sutkus; 7/05-8/05, Nicole Turner; 9/05-10/05, Marika Wolfe; 10/05-11/05, Kristine Schwinof; 1/6-2/06, Don Chang; 2/06-3/06, David Verschueren; 3/06, Nicole Christiansen, visiting MS-III, Creighton University School of Medicine; 3/06-4/06, Siddhartha Kapnadak; 5/06-6/06, Emily Dinges; 7/06-8/06, Beech Burns; 8/06-9/06, Viktoriya Wolfer; 2/07-3/07, Monika Arora; 3/07-4/07, Lyudmila Morozova; 7/07-8/07, John Scarborough; 8/07-9/07, Conrad Liang; 9/07-10/07, Joy Bang, visiting MS-III, New England College of Osteopathic Medicine; 10/07-11/07, James Dayton; 12/07-1/08, Brandon Peters, MS-IV, 4th year sleep medicine elective; 2/08-3/08, Faisal Siddiqui; 3/08-4/08, Samuel Bobek; 4/08-5/08, Matt Clausen; 7/08-7/08, Ju Yon Sophie Yi; 9/10-10/10, Daniel Lamb, MS-IV, 4th year sleep medicine elective

5. Clinical supervision of a fourth year psychiatry resident in the Sleep Disorders Medicine Clinic, 4th year elective (quarter to half day per week).

Larry Mak, M.D., 1/2010 - 3/2010
Jay Augsburg, M.D., 7/2010 - 12/2010
Laura Brogach, M.D., 7/2015-12/2015
Timothy Hanson, M.D., 7/2015-12/2015
Kelly Cleaves, M.D., 1/2016-3/2016
Cara Niemeier, M.D., 4/2016-7/2016
Elizabeth Schmick, M.D., 7/2016-9/2016
Pia Quimson, M.D., 10/2016-12/2016
Saul Farris, M.D., 1/2017-2/2017
Rachel Morenz, M.D., 1/2017- 6/2017

6. Past Lectures:

Psychology Post-doctoral interns:

Insomnia 7/10/13, 8/13/14, 5/4/16

Psychiatric Nurse Practitioners, VHAPORHCS

Sleep disorders, 2/6/14, 4/7/16

Psychosomatic and Geropsychiatry Fellows, VHAPORHCS

Sleep Apnea, 2/6/15

Parasomnias, 4/17/15 & 5/5/17

VA Portland Health Care System (VHAPORHCS) Primary Care Providers

Insomnia, 4/29/15

Project ECHO, Oregon Health & Science University

Insomnia, 5/7/15, 2/18/16, 2/16/17

Internal Medicine Residents' Ambulatory Curriculum

Sleep Apnea, 2/12/16, 2/19/16, 2/26/16 & 3/4/16

VA Portland Health Care System (VHAPORHCS) Primary Care Providers

Sleep Apnea, 4/27/16

Geriatric Sleep Human Growth and Development, MS-I

History of Sleep Medicine, MS-II

VA PTSD Team, Sleep Disorders, 4/25/18

OHSU School of Public Health, Occupational Health Course, Lecture on Sleep

Disorders, 5/7/18, 5/6/19

Evidence Based Medicine, PGY-2 and 3, “Diagnosis and Diagnostic Tests”, covered sensitivity, specificity, likelihood ratios, etc., 5/2008-4/2011

7. Faculty Research Mentor:

General Clinical Research Center, Mentored Medical Student Clinical Research Program (MMSP); Brandon Peters (MS-I); Summer, 2005

Systems, Processes, & Homeostasis (Physiology & Pharmacology) Student research project (SRP) 2006; Co-Mentor with David Grandy, Ph.D.; First Year Medical Students: Matthew Clausen, Christopher Baumann, Scott Davis, James Dayton, Shereen Katrak, Megan Locher, Jesse Madden, Casey Murphy, Amara Sheppard and Melissa Yamauchi.

Systems, Processes, & Homeostasis (Physiology & Pharmacology) Student research project (SRP) 2007; Mentor; First Year Medical Students: Erin Braithwaite, Julie Chinn, Stacy de la Motte, Morgan Garvin, Evan Los, Ilan Maizlin, William Ruegg, Maegan Sauvageau, Abigail Vautrain.

Systems, Processes, & Homeostasis (Physiology & Pharmacology) Student research project (SRP) 2008; Mentor; First Year Medical Students: Leah Gordon, Mini Zhang, Adam Glaser, Lily Wittich, Ricky Chen, Naomi Fishman, Linh Le, Yossi Berlow, Melissa Kjos, and Jessica Carlson.

Systems, Processes, & Homeostasis (Physiology & Pharmacology) Student research project (SRP) 2009; Mentor; First Year Medical Students: Terrence Lee, Matthew Snodgrass, Emmy Davison, Nora Switchenko, Donna Kang, and Anne Fang

8. Faculty Mentor: April Sweeney, M.D. (Psychiatry PGY-1, 2007-2008)

9. Resident and Faculty Case Conference: 8/21/07 Faculty Presenter

Scholarship of Teaching:

Curriculum Development

Participated in the Evidence Based Medicine course development. Committee members included Sahana Misra, Erick Turner, and Pritham Raj.

Cognitive Behavioral Therapy for Insomnia (CBT-I) group therapy. Developed a new, structured, 8-week CBT-I group therapy program for Veterans with complex insomnia along with Katherine Chiba, MSW.

Educational Conference Presentations

“Advances in Management of Chronobiological Disorders.” Northwest Hospital & Medical Center CME conference: Advances in Diagnosis and Management of Sleep Disorders, Seattle, WA, February 2004.

“Circadian Rhythms in the Blind.” OHSU Department of Psychiatry Grand Rounds, Portland, OR, August 25, 2005

“Hypnotics.” Oregon Psychiatric Association, Portland, OR, March 3, 2007.

“Overview of Sleep Medicine.” Oregon Health & Science University CME conference: Evaluation and Treatment of Sleep Disorders: A Practical Review, Portland, OR, May 5, 2007.

“Diagnosis and Treatment of Insomnia.” Oregon Health & Science University Family Medicine Review, Portland, OR, February 27, 2008.

“Sleep-Related Eating Disorder (SRED) and Night-Eating Syndrome (NES).” Columbia River Eating Disorders Network (CREDN), Providence Hospital, Portland, OR, May 8, 2008.

“Sleep Disorders: Focus on Insomnia.” Mental Health and Primary Care Conference, Bend, OR, October 4, 2008.

“Diagnosis and Treatment of Insomnia.” Oregon Health & Science University Family Medicine Review, Portland, OR, February 10, 2009.

“Diagnosis and Treatment of Insomnia.” Oregon Health & Science University Family Medicine Review, Portland, OR, February 22, 2010.

“Diagnosis and Treatment of Insomnia.” Oregon Health & Science University Primary Care Review, Portland, OR, February 7, 2011.

“Sleep Apnea and Insomnia.” Oregon Health & Science University Internal Medicine Review, Portland, OR, March 8, 2013.

“Sleep Apnea and Insomnia.” Oregon Health & Science University Primary Care Review, Portland, OR, February 9, 2015.

“Insomnia.” Oregon Health & Science University Adult Mental Health Update: Strategies for Primary Care, Portland, OR, March, 15, 2019.

“Insomnia.” Oregon Health & Science University Primary Care Review, Portland, OR, April 11, 2019.

“Insomnia.” Oregon Health & Science University Adult Mental Health Update: Strategies for Primary Care, Portland, OR, September, 13, 2019.

EXHIBIT A – *Curriculum Vitae*

DAVID J. GREENBLATT, M.D.

Current Title:

Louis Lasagna Endowed Professor, Department of Immunology (formerly the Department of Pharmacology and Experimental Therapeutics); Professor of Psychiatry, Medicine, and Anesthesia, Tufts University School of Medicine; Special and Scientific Staff (Research), Tufts Medical Center, Boston MA

Education and Training:

1966	B.A. Amherst College (magna cum laude)
1970	M.D. Harvard Medical School
1970-1971	Medical Intern, Montefiore Hospital and Medical Center, Bronx, NY
1971-1972	Assistant Medical Resident, Harvard Medical Service, Boston City Hospital
1972-1974	Research Fellow in Pharmacology, Harvard Medical School; Fellow in Medicine (Clinical Pharmacology), Massachusetts General Hospital

Professional Appointments:

Harvard Medical School and Massachusetts General Hospital

1974-1979	Assistant Professor of Medicine, Harvard Medical School; Assistant in Medicine, Massachusetts General Hospital
1976-1979	Chief, Clinical Pharmacology Unit, Massachusetts General Hospital

Tufts University School of Medicine (TUSM) and Tufts Medical Center (TMC):

1979-present	Professor of Psychiatry, Tufts University School of Medicine, Boston MA (TUSM)
1979-2015	Associate Medical Staff, Tufts Medical Center (TMC)
2015-	Special and Scientific Staff (Research), TMC
1979-1984	Associate Professor of Medicine, TUSM
1983-1996, 2001-2002	Chair, Institutional Review Board, TMC/TUSM
1984-present	Professor of Medicine, TUSM
1988-1991	Professor of Pharmacology, TUSM
1991-present	Professor of Pharmacology and Experimental Therapeutics (with tenure), TUSM
1994-2010	Chairman, Department of Pharmacology and Experimental Therapeutics, TUSM
1995-present	Professor of Anesthesia, TUSM
1995-2002	Program Director, General Clinical Research Center, TMC
1997-present	Louis Lasagna Endowed Professor of Pharmacology and Experimental Therapeutics, TUSM
2002-2010	Associate Program Director, Clinical/Translational Research Center, TMC/TUSM

Awards and Honors:

1972-74	Research Fellow of the Medical Foundation, Inc., Boston
1978-87	Pfizer Lecturer in Clinical Pharmacology (at various institutions)
1980	Rawls-Palmer Progress in Medicine Award and Lecture, American Society for Clinical Pharmacology and Therapeutics
1980	Clinical Pharmacology Unit Developmental Grant, Pharmaceutical Manufacturers' Association Foundation, Washington, D.C.
1981	Wellcome Visiting Professor in the Basic Medical Sciences (the Burroughs Wellcome Fund and Federation of American Societies

for Experimental Biology),
East Carolina University School of Medicine, Greenville, N.C.

- 1983 Paul Ehrlich Visiting Professor of Clinical Pharmacology,
University of Miami School of Medicine
- 1984 Sterling Visiting Professor,
Boston University School of Medicine
- 1985 The McKeen Cattell Award,
(with Drs. O. Bellmann, H.R. Ochs, and M. Knüchel)
American College of Clinical Pharmacology
- 1988 T. George Bidder Distinguished Lectureship in Psychopharmacology,
University of California at Los Angeles
- 1997 Pfizer Visiting Professor of Clinical Pharmacology,
Morehouse University School of Medicine, Atlanta, GA
- 2001 Distinguished Service Award,
American College of Clinical Pharmacology
- 2002 Distinguished Investigator Award,
American College of Clinical Pharmacology
- 2005 Research Achievement Award in Clinical Sciences,
American Association of Pharmaceutical Scientists
- 2013 Outstanding Speaker Award,
American Association for Clinical Chemistry
- 2015 Distinguished Faculty Award,
Tufts University School of Medicine
- 2016 Award in Excellence in Clinical Pharmacology,
Pharmaceutical Research and Manufacturers of America Foundation
- 2016 Man of Good Conscience Award,
Association of Women Psychiatrists

Certification

- 1991 American Board of Clinical Pharmacology, Inc.

Editorial Boards

Journal of Clinical Psychopharmacology (Co-Editor-in-Chief)

Clinical Pharmacology in Drug Development (Editor-in-Chief)

Journal of Clinical Pharmacology

British Journal of Clinical Pharmacology (2011-2016)

Biopharmaceutics and Drug Disposition

Xenobiotica

Neuropsychopharmacology (1986-1990)

Drug Investigation

Drugs and Aging

Pharmacology and Toxicology

Drugs and Therapy Perspectives

Professional Societies

American Society for Clinical Investigation (Emeritus)

American Society for Pharmacology and Experimental Therapeutics

American Federation for Clinical Research

American Society for Clinical Pharmacology and Therapeutics
Board of Directors, 1983-85

American College of Clinical Pharmacology
Board of Regents, 1981-85, 1987-91;
Honorary Regent, 1994-;
President-Elect, 1994-1996;
President, 1996-1998

American College of Neuropsychopharmacology (Fellow) (1974-2011)

International Society for the Study of Xenobiotics

British Pharmacological Society

ORIGINAL RESEARCH ARTICLES

1. Tursky B, Greenblatt DJ: Local vascular and thermal changes that accompany electric shock. Psychophysiology 3:371-380, 1967.
2. Greenblatt DJ, DiMascio A, Messier M, Stotsky B: Magnesium pemoline and job performance in mentally handicapped workers. Clinical Pharmacology and Therapeutics 10:530-533, 1969.
3. Greenblatt DJ, Tursky B: Local vascular and impedance changes induced by electric shock. American Journal of Physiology 216:712-718, 1969.
4. Tursky B, Greenblatt DJ, O'Connell DN: Electrocutaneous threshold changes produced by electric shock. Psychophysiology 7:490-498, 1970.
5. Greenblatt DJ, Shader RI: Psychopharmacologic management of anxiety in the cardiac patient. Psychiatry in Medicine 2:490-498, 1970.
6. Greenblatt DJ, Shader RI: Meprobamate: a study of irrational drug use. American Journal of Psychiatry 127:1297-1303, 1971.
7. Greenblatt DJ, Shader RI: The clinical choice of sedative-hypnotics. Annals of Internal Medicine 77:91-100, 1972.
8. Greenblatt DJ, Shader RI: On the psychopharmacology of beta adrenergic blockade. Current Therapeutic Research 14:615-625, 1972.
9. Greenblatt DJ, Koch-Weser J: Adverse reactions to spironolactone: a report from the Boston Collaborative Drug Surveillance Program. Journal of the American Medical Association 225:40-43, 1973.
10. Greenblatt DJ, Shader RI: Anticholinergics. New England Journal of Medicine 288:1215-1219, 1973.
11. Greenblatt DJ, Koch-Weser J: Adverse reactions to propranolol in hospitalized medical patients: a report from the Boston Collaborative Drug Surveillance Program. American Heart Journal 86:478-484, 1973.
12. Greenblatt DJ, Koch-Weser J: Adverse reactions to intravenous diazepam: a report from the Boston Collaborative Drug Surveillance Program. American Journal of Medical Sciences 266:261-266, 1973.

13. Greenblatt DJ, Duhme DW, Koch-Weser J, Smith TW: Evaluation of digoxin bioavailability in single-dose studies. New England Journal of Medicine 289:651-654, 1973.
14. Greenblatt DJ, Koch-Weser J: Adverse reactions to beta-adrenergic receptor blocking drugs: a report from the Boston Collaborative Drug Surveillance Program. Drugs 7:118-129, 1974.
15. Greenblatt DJ, Shader RI: Drug abuse and the emergency room physician. American Journal of Psychiatry 131:559-562, 1974.
16. Duhme DW, Greenblatt DJ, Koch-Weser J: Reduction of digoxin toxicity associated with measurement of serum levels: a report from the Boston Collaborative Drug Surveillance Program. Annals of Internal Medicine 80:516-519, 1974.
17. Koch-Weser J, Duhme DW, Greenblatt DJ: Influence of serum digoxin concentration measurements on frequency of digitoxicity. Clinical Pharmacology and Therapeutics 16:284-287, 1974.
18. Greenblatt DJ, Duhme DW, Koch-Weser J, Smith TW: Intravenous digoxin as a bioavailability standard: slow infusion and rapid injection. Clinical Pharmacology and Therapeutics 15:510-513, 1974.
19. Greenblatt DJ, Koch-Weser J: Oral contraceptives and hypertension: a report from the Boston Collaborative Drug Surveillance Program. Obstetrics and Gynecology 44:412-417, 1974.
20. Greenblatt DJ, Duhme DW, Koch-Weser J, Smith TW: Equivalent bioavailability from digoxin elixir and rapid-dissolution tablets. Journal of the American Medical Association 229:1774-1776, 1974.
21. Greenblatt DJ, Shader RI, Koch-Weser J. Pharmacokinetic determinants of the response to single doses of chlordiazepoxide. American Journal of Psychiatry 131:1395-1397, 1974.
22. Greenblatt DJ, Koch-Weser J: Clinical toxicity of chlordiazepoxide and diazepam in relation to serum albumin concentration: a report from the Boston Collaborative Drug Surveillance Program. European Journal of Clinical Pharmacology 7:259-262, 1974.
23. Greenblatt DJ, Duhme DW, Koch-Weser J, Smith TW: Bioavailability of digoxin tablets and elixir in the fasting and postprandial states. Clinical Pharmacology and Therapeutics 16:444-448, 1974.
24. Greenblatt DJ, Shader RI, Koch-Weser J, Franke K: Slow absorption of intramuscular chlordiazepoxide. New England Journal of Medicine 291:1116-1118, 1974.

25. Greenblatt DJ, Duhme DW, Koch-Weser J, Smith TW: Comparison of one- and six-day urinary digoxin excretion in single-dose bioavailability studies. Clinical Pharmacology and Therapeutics 16:813-816, 1974.
26. Greenblatt DJ, Shader RI: Benzodiazepines. New England Journal of Medicine 291:1011-1015, 1239-1241, 1974.
27. Greenblatt DJ, Shader RI, Koch-Weser J: Flurazepam hydrochloride. Clinical Pharmacology and Therapeutics 17:1-14, 1975.
28. Sokol GH, Greenblatt DJ, Littman P, Franke K, Koch-Weser J: Chlordiazepoxide metabolism in mice following hepatic irradiation. Pharmacology 13:248-251, 1975.
29. Greenblatt DJ, Shader RI, Koch-Weser J: Psychotropic drug use in the Boston area: a report from the Boston Collaborative Drug Surveillance program. Archives of General Psychiatry 32:518-521, 1975.
30. Shader RI, Greenblatt DJ, Salzman C, Kochansky GE, Harmatz JS: Benzodiazepines: safety and toxicity. Diseases of the Nervous System 36(No. 5, Sect. 2):23-26, (May) 1975.
31. Greenblatt DJ, Shader RI, Koch-Weser J: Pharmacokinetics in clinical medicine: oxazepam versus other benzodiazepines. Diseases of the Nervous System 36(No. 5, Sect. 2):6-13, (May) 1975.
32. Greenblatt DJ, Shader RI, Koch-Weser J: Flurazepam hydrochloride, a benzodiazepine hypnotic. Annals of Internal Medicine 83:237-241, 1975.
33. Koup JR, Greenblatt DJ, Jusko WJ, Smith TW, Koch-Weser J: Pharmacokinetics of digoxin in normal subjects after intravenous bolus and infusion doses. Journal of Pharmacokinetics and Biopharmaceutics 3:181-192, 1975.
34. Greenblatt DJ, Koch-Weser J: Clinical pharmacokinetics. New England Journal of Medicine 293:702-705, 964-970, 1975.
35. Greenblatt DJ, Allen MD, Koch-Weser J: Accidental poisoning with psychotropic drugs in children. American Journal of Diseases in Children 130:507-511, 1976.
36. Greenblatt DJ, Shader RI, Koch-Weser J. Serum creatine phosphokinase concentrations after intramuscular chlordiazepoxide and its solvent. Journal of Clinical Pharmacology 16:118-121, 1976.
37. Greenblatt DJ, Bolognini V, Koch-Weser J, Harmatz JS: Pharmacokinetic approach to the clinical use of lidocaine intravenously. Journal of the American Medical Association 236:273-277, 1976.

38. Pfeifer HJ, Greenblatt DJ, Koch-Weser J: Clinical use and toxicity of intravenous lidocaine: a report from the Boston Collaborative Drug Surveillance Program. American Heart Journal 92:168-173, 1976.
39. Greenblatt DJ, Duhme DW, Koch-Weser J, Smith TW: Assessment of methodology in single-dose studies of digoxin bioavailability. Pharmacology 14:182-190, 1976.
40. Greenblatt DJ, Shader RI, Lofgren S: Rational psychopharmacology for patients with medical diseases. Annual Review of Medicine 27:407-420, 1976.
41. Greenblatt DJ, Shader RI, Harmatz JS, Franke K, Koch-Weser J: Influence of magnesium and aluminum hydroxide mixture on chlordiazepoxide absorption. Clinical Pharmacology and Therapeutics 19:234-239, 1976.
42. Greenblatt DJ, Smith TW, Koch-Weser J: Bioavailability of drugs: the digoxin dilemma. Clinical Pharmacokinetics 1:36-51, 1976.
43. Greenblatt DJ, Ransil BJ, Harmatz JS, Smith TW, Duhme DW, Koch-Weser J: Variability of 24-hour urinary creatinine excretion by normal subjects. Journal of Clinical Pharmacology 16:321-328, 1976.
44. Stanski DR, Greenblatt DJ, Lappas DG, Koch-Weser J, Lowenstein E: Kinetics of high dose intravenous morphine in cardiac surgery patients. Clinical Pharmacology and Therapeutics 19:752-756, 1976.
45. Pfeifer HJ, Greenblatt DJ, Koch-Weser J: Clinical toxicity of reserpine in hospitalized patients: a report from the Boston Collaborative Drug Surveillance Program. American Journal of Medical Sciences 271:269-276, 1976.
46. DiMascio A, Bernardo DL, Greenblatt DJ, Marder JE: A controlled trial of amantadine in drug-induced extrapyramidal disorders. Archives of General Psychiatry 33:599-602, 1976.
47. Greenblatt DJ, Schillings RT, Kyriakopoulos AA, Shader RI, Sisenwine SF, Knowles JA, Ruelius HW: Clinical pharmacokinetics of lorazepam. I. Absorption and disposition of oral 14C-lorazepam. Clinical Pharmacology and Therapeutics 20:329-341, 1976.
48. Stanski DR, Greenblatt DJ, Selwyn A, Shader RI, Franke K, Koch-Weser J: Plasma and cerebrospinal fluid concentrations of chlordiazepoxide and its metabolites in surgical patients. Clinical Pharmacology and Therapeutics 20:571-578, 1976.
49. Greenblatt DJ, Koch-Weser J: Intramuscular injection of drugs. New England Journal of Medicine 295:542-546, 1976.

50. Greenblatt DJ, Duhme DW, Allen MD, Koch-Weser J: Clinical toxicity of furosemide in hospitalized patients: a report from the Boston Collaborative Drug Surveillance Program. American Heart Journal 94:6-13, 1977.
51. Allen MD, Greenblatt DJ: Accidental salicylate poisoning. Paediatrician 6:244-249, 1977.
52. Greenblatt DJ, Shader RI, Harmatz JS, Franke K, Koch-Weser J: Absorption rate, blood concentrations, and early response to oral chlordiazepoxide. American Journal of Psychiatry 134:559-562, 1977.
53. Greenblatt DJ, Joyce TH, Comer WH, Knowles JA, Shader RI, Kyriakopoulos AA, MacLaughlin DS, Ruelius HW: Clinical pharmacokinetics of lorazepam. II. Intramuscular injection. Clinical Pharmacology and Therapeutics 21:222-230, 1977.
54. Ransil BJ, Greenblatt DJ, Koch-Weser J: Evidence for systematic temporal variation in 24-hour urinary creatinine excretion. Journal of Clinical Pharmacology 17:108-119, 1977.
55. Greenblatt DJ, Comer WH, Elliott HW, Shader RI, Knowles JA, Ruelius HW: Clinical pharmacokinetics of lorazepam. III. Intravenous injection (preliminary report). Journal of Clinical Pharmacology 17:490-494, 1977.
56. Greenblatt DJ, Knowles JA, Comer WN, Shader RI, Harmatz JS, Ruelius HW: Clinical pharmacokinetics of lorazepam. IV. Long-term oral administration. Journal of Clinical Pharmacology 17:495-500, 1977.
57. Ameer B, Greenblatt DJ: Acetaminophen. Annals of Internal Medicine 87:202-209, 1977.
58. Greenblatt DJ, Pfeifer HJ, Ochs HR, Franke K, MacLaughlin DS, Smith TW, Koch-Weser J: Pharmacokinetics of quinidine in humans after intravenous, intramuscular and oral administration. Journal of Pharmacology and Experimental Therapeutics 202:365-378, 1977.
59. Greenblatt DJ, Allen MD, Shader RI: Toxicity of high-dose flurazepam in the elderly. Clinical Pharmacology and Therapeutics 21:355-361, 1977.
60. Greenblatt DJ, DiMascio A, Harmatz JS, Bernardo DL, Marder JR: Pharmacokinetics and clinical effects of amantadine in drug-induced extrapyramidal symptoms. Journal of Clinical Pharmacology 17:704-708, 1977.
61. Greenblatt DJ, Allen MD, Noel BJ, Shader RI: Acute overdosage with benzodiazepine derivatives. Clinical Pharmacology and Therapeutics 21:497-514, 1977.

62. Shader RI, Greenblatt DJ: Clinical implications of benzodiazepine pharmacokinetics. American Journal of Psychiatry 134:652-656, 1977.
63. Pfeifer HJ, Greenblatt DJ, Koch-Weser J: Adverse reactions to practolol in hospitalized patients: a report from the Boston Collaborative Drug Surveillance Program. European Journal of Clinical Pharmacology 12:167-170, 1977.
64. Allen MD, Greenblatt DJ, Noel BJ: Meprobamate overdosage: a continuing problem. Clinical Toxicology 11:501-516, 1977.
65. Greenblatt DJ, Harmatz JS, Stanski DR, Shader RI, Franke K, Koch-Weser J: Factors influencing blood concentrations of chlordiazepoxide: a use of multiple regression analysis. Psychopharmacology 54:277-282, 1977.
66. Greenblatt DJ, Shader RI, Franke K, MacLaughlin DS, Ransil BJ, Koch-Weser J : Kinetics of intravenous chlordiazepoxide: sex differences in drug distribution. Clinical Pharmacology and Therapeutics 22:893-903, 1977.
67. Shader RI, Greenblatt DJ, Harmatz JS, Franke K, Koch-Weser J: Absorption and disposition of chlordiazepoxide in young and elderly male volunteers. Journal of Clinical Pharmacology 17:709-718, 1977.
68. Greenblatt DJ, Harmatz JS, Shader RI: Sex differences in diazepam protein binding in patients with renal insufficiency. Pharmacology 16:26-29, 1978.
69. Ochs HR, Greenblatt DJ, Bodem G, Smith TW: Sprinolactone. American Heart Journal 96:389-400, 1978.
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BOOKS

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- B4. Davis JM, Greenblatt DJ (eds): Psychopharmacology Update: New and Neglected Areas. New York, Grune and Stratton, 1979.
- B5. Miller RR, Greenblatt DJ (eds): Handbook of Drug Therapy. New York, Elsevier/North Holland, 1979.
- B6. Miller RR, Greenblatt DJ (eds): Drug Therapy Reviews, Vol. 2, New York, Elsevier/North Holland, 1979.
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- B11. Ciraulo DA, Shader RI, Greenblatt DJ, Creelman W (eds): Drug Interactions in Psychiatry. Baltimore, Williams and Wilkins, 1989. Second Edition, 1995.
- B12. Jacobson SA, Pies RW, Greenblatt DJ: Handbook of Geriatric Psychopharmacology. Washington DC, American Psychiatric Publishing, Inc., 2002.

EXHIBIT A – *Curriculum Vitae*

Deborah A. Jaskot

Deborah Jaskot & Associates LLC

106 Shetland Way
Collegeville, PA 19426

[REDACTED]
[REDACTED]

Education

B. S. Biology, University of Scranton, Scranton, PA

M. S. Biochemistry, University of Scranton, Scranton, PA

Relevant Career History

1986 – 1989 Cord Laboratories (now Sandoz), Broomfield, CO

Drug Regulatory Affairs Coordinator

June 1989 – November 2012 Teva Pharmaceuticals USA

All Positions in Regulatory Affairs

1989 – 1990 Regulatory Affairs Associate

1990 – 1991 Sr. Associate

1991 – 1993 Manager

1993 – 1994 Associate Director

1994 – 1996 Director

1996 – 1999 Sr. Director

1999 – 2004 Executive Director

2004 – 2009 V.P., U. S. Generic RA

2009 – 2012 V.P., U. S. Generic RA and NA Policy

In my most recent position at Teva I was responsible for impacting legislation, regulation, and other policy that would impact Teva's operations throughout North America. This included working closely with Teva's Legal Affairs staff and Government Affairs office in Washington as

well as visits with Congressional staffers to educate them on the impact of proposed legislation to their constituent patients.

Additionally, it was important to seek the proper balance of interests such that all aspects of Teva's business, branded and generics, were considered prior to taking a position. This was in addition to overseeing a staff of 140 in the routine generic drug submission process and maintenance as well as providing strategy and oversight for a considerable number of 505(b)(2) applications. Close collaboration with all of Teva's R&D groups throughout the development process resulted in considerable success in the approval and launch of generic as well as 'added value' generic products.

Significant Achievement Summary

Interacted collaboratively and positively with FDA staff to achieve hundreds of ANDA approvals for a vast variety of drugs and dosage forms

Designed regulatory strategies to routinely ensure timely approvals which provided quality, affordable alternatives to the consuming public

Excellent, longstanding working relationship with the Office of Generic Drugs and Office of Pharmaceutical Science as the primary liaison between Teva and FDA

Designed creative and effective scientific and regulatory responses to citizen petitions which sought to delay and/or derail generic drug approval

Effectively worked through complex regulatory and legal hurdles that often emerged as unintended consequences of amended legislation

Participated in the successful integration of seven acquired companies creating synergies and added value while focusing on maintaining high standards of ethical conduct throughout the growing organization

Built a high functioning staff of 140 regulatory professionals, para-professionals and administrative persons at three sites, leading in the interpretation and implementation of regulations for pre and post approval regulatory activities

Acted as a lead industry negotiator in the Generic Drug User Fee development process as well as the Biosimilars User Fee development process

Given approximately 85 depositions in both patent and product liability cases

Feb. 2013 – present Deborah Jaskot & Associates LLC

Currently providing consulting services in regulatory affairs to a broad range of clients. Areas covered include pharmaceutical development, response strategies for review letters, negotiating submission strategies with FDA, advising on post approval changes including data burden and mode of submission, and assisting in addressing inspection findings.

Having testified in 85 – 90 depositions during my career at Teva, I have experience in patent, liability and antitrust cases. As an independent consultant I have acted as an expert witness and issued expert reports.



Attachment A-1 (Updated): McDuff CV

DeForest McDuff, Ph.D.

November 2021

DeForest McDuff, Ph.D. is an expert economist, adjunct professor of economics, and experienced expert witness, with extensive experience in consulting, finance, and business. Dr. McDuff's expert opinions have been cited and relied upon by clients, courts, and government agencies. Dr. McDuff was named in the IAM Patent 1000 as a top expert witness for patent cases in 2020. Dr. McDuff co-founded Insight Economics in 2017.

Dr. McDuff provides economic consulting and testimony in many areas, including:

- Economic damages: lost profits, unjust enrichment, reasonable royalty, loss of value, loss of reputation, business impact, and other issues
- Intellectual property: patents, trademarks, trade secrets, copyrights, licensing
- Antitrust: monopolization, price discrimination, tying, price fixing, mergers
- Competition: economic harm, market definition, unfair competition, false advertising
- Legal issues: class action, class certification, irreparable harm, commercial success
- Other areas: valuation, financial analysis, labor, employment, lost wages, and more

Dr. McDuff's expert witness experience includes more than 100 expert reports, 60 expert depositions, and 20 trials and hearings in courts across the country. His consulting experience outside the courtroom includes regulatory analysis, fair market value, licensing, negotiation, pricing, business strategy, product launches, strategic analysis, and a range of other topics.

Dr. McDuff earned a Ph.D. in Economics from Princeton University, where he received a National Science Foundation Graduate Research Fellowship (awarded to 25 graduate students in economics nationwide each year) for his academic research in financial economics and applied microeconomics. He has published in peer-reviewed academic journals and widely reviewed industry publications. Dr. McDuff graduated *summa cum laude* with a B.A. in economics and a B.S. mathematics from the University of Maryland.

Dr. McDuff is currently appointed as an Adjunct Teaching Professor in the Department of Economics at the University of North Carolina at Chapel Hill. Dr. McDuff is also the co-founder of Integrity Seminars, an online company dedicated to teaching academic integrity to college students since 2006. The company offers the Academic Integrity Seminar, which is a personalized online educational intervention administered to more than 100 colleges and universities nationwide to promote the importance of social trust and mutual obligation in personal, academic, and economic relationships.

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Professional Experience

Insight Economics (www.insighteconomics.com). San Diego, CA and Raleigh, NC. Co-Founder and Partner, 2017 to present.

University of North Carolina at Chapel Hill. Chapel Hill, NC. Teaching Assistant Professor, Department of Economics, 2020 to present.

Integrity Seminars (www.integrityseminar.org, formerly Academic Integrity Seminar). Co-Founder and Partner, 2006 to present.

Intensity (formerly Quant Economics). San Diego, CA and Boston, MA. Economist from 2009 to 2012, Senior Economist from 2012 to 2013, Vice President from 2013 to 2017, Head of Boston Office from 2015 to 2017.

JPMorgan Chase. New York NY. Trading Analyst, 2006 to 2007.

Princeton University. Princeton NJ. Economic Research Assistant, 2004 to 2006.

Education

Ph.D. in Economics, Princeton University, 2009.

M.A. in Economics, Princeton University, 2006.

B.A. in Economics, University of Maryland, College Park, *summa cum laude*, 2004.

B.S. in Mathematics, University of Maryland, College Park, *summa cum laude*, 2004.

Professional Memberships

American Economic Association (AEA).

Licensing Executives Society (LES).

Publications

McDuff, DeForest, Mickey Ferri, and Noah Brennan: "Patents and Antitrust in the Pharmaceuticals Industry" (2021) California Antitrust and Unfair Competition Law, forthcoming.

McDuff, DeForest, Mickey Ferri, and Noah Brennan: "Thinking Economically About Blocking Patents: Did Acorda Create a New Paradigm?" (2020) Landslide, Volume 12, Number 4, 42-45.



McDuff, DeForest and Nathan Koterba: "Formal Fridays: 60+ Strategies for Standing Out & Getting Promoted," (2018) Amazon Publishing.

McDuff, DeForest, Gary Pavela, and Donald McCabe: "Updated: Ten Principles of Academic Integrity for Faculty," (2017) Integrity Seminars Resource.

McDuff, DeForest, Ryan Andrews, and Matthew Brundage: "Thinking Economically About Commercial Success," (2017) Landslide, Volume 9, Number 4, 37-40.

McDuff, DeForest: "Splitting the Atom: Economic Methodologies for Profit Sharing in Reasonable Royalty Analysis," (2016) les Nouvelles June 2016, 70-73.

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McDuff, DeForest, Ryan Sullivan, and Justin Skinner: "Downgrade to 'Neutral': A Diminishing Role of the Georgia-Pacific Factors in Reasonable Royalty Analyses," (2015) les Nouvelles 50(3), 134-137. Licensing Executives Society Article of the Month: March 2016.

McDuff, DeForest and Ryan Sullivan: "AstraZeneca and Damages In 'At-Risk' Generic Drug Launches," April 28, 2015, Law360.

McDuff, DeForest and Justin Skinner: "Reasonable Royalties: All About that Base ... Or That Rate," December 18, 2014, Law360.

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McDuff, DeForest and Justin Skinner: "Apple v. Motorola May Help Defenders of Daubert Challenges" with Justin Skinner, May 21, 2014, Law360.

McDuff, DeForest: "Home Price Risk, Local Market Shocks, and Index Hedging," (2012) The Journal of Real Estate Finance and Economics 45(1), 212-237.

McDuff, DeForest: "Demand Substitution Across U.S. Cities: Observable Similarity and Home Price Correlation," (2011) Journal of Urban Economics 70(1), 1-14.

McDuff, DeForest: "Quality, Tuition, and Applications to In-State Public Colleges," (2007) Economics of Education Review 26(4), 433-449.

McDuff, DeForest: "Analyzing Income and Happiness: The Effects of Placing Too Much Emphasis on Income in a Job" (2005), Princeton manuscript.



Awards

IAM Patent 1000: Top Expert Witnesses. Awarded to top expert witnesses nationwide (approximately 80-90 experts) with expertise in economic patent analysis, 2020.

Towbes Teaching Prize for Outstanding Teaching. Awarded to top 4 teaching assistants in the economics department, Princeton University, 2006.

National Science Foundation Graduate Research Fellowship. Awarded to 25 graduate students in economics nationwide each year, Princeton University, 2005.

Princeton University Graduate Research Fellowship. Full tuition fellowship and stipend for graduate research, Princeton University, 2004.

Dillard Prize. Awarded to top undergraduate in economics, University of Maryland at College Park, 2004.

Speaking Engagements

"Physician Finances: From Resident to Attending," Harvard Residency Morning Conference, Boston MA, 2019; Duke University Residency Morning Conference, Durham NC, 2020.

"Price Optimization in E-Commerce," Presenter, Global Big Data Conference, Boston MA, 2016.

"Damages Whirlwind: Navigating Reasonable Royalties in 2015," Presenter, Boston Patent Law Association, Boston MA, 2015.

"Asset Valuation and Patent Monetization: A Review of Valuation Methods and Transaction Structures," Presenter, Law Seminars International, San Francisco CA, 2015.

"Jury Trials for At-Risk Generic Launches," Presenter, Continuing Legal Education, Los Angeles CA, 2015.

"Careers for PhDs in Start-ups," Panelist, University of California at San Diego, San Diego CA, 2014.

"How to Prove Reasonable Royalty in Patent Damages," Panelist, The Knowledge Congress, San Diego CA, 2013.

"Careers in Economics and Finance," Presenter, University of California at San Diego, San Diego CA, 2010.

"Home Price Risk, Local Market Shocks, and Index Hedging," Presenter, National Bureau of Economic Research, Boston MA, 2008.



Expert Testimony (4 Years)

1. Gentex Corporation v. Galvion Ltd., Galvion Inc., United States District Court, District of Delaware, Case No. 19-00921-MN. Evaluation of patent damages including reasonable royalty, lost profits, unjust enrichment, and contract royalties for military helmet equipment.
2. Salix Pharmaceuticals, Ltd.; Salix Pharmaceuticals, Inc.; Bausch Health Ireland Ltd.; and Alfasigma S.P.A. v. Norwich Pharmaceuticals, Inc., United States District Court, District of Delaware, Case No. 20-00430-RGA. Evaluation of commercial success related to Xifaxan (rifaximin) for treatment of hepatic encephalopathy and irritable bowel syndrome with diarrhea. Expert report.
3. Volterra Semiconductor LLC v. Monolithic Power Systems, Inc., United States District Court, District of Delaware, Case No. 1:19-cv-02240. Evaluation of patent infringement, economic damages, and reasonable royalty related to integrated chip power solutions. Expert report (x2), deposition.
4. Horizon Medicines LLC v. Alkem Laboratories Ltd., United States District Court, District of Delaware, Case No. 1:18-cv-01014. Evaluation of irreparable harm, balance of hardships, and public interest with respect to patent infringement and the commercial performance of Duexis (ibuprofen famotidine). Expert declaration.
5. Rubicon Research Private Limited v. Kartha Pharmaceuticals Inc., and Manoj Babu Mazhuvancheril; Zakłady Farmaceutyczne Polpharma S.A. v. Kartha Pharmaceuticals, Inc., United States District Court, Western District of North Carolina (Charlotte), Case No. 3:21-cv-00129-MOC-DSK; 3:21-cv-00129-GCM. Evaluation of irreparable harm, public interest, balance of hardships, and bond related to trade secret misappropriation and breach of contract in pharmaceutical product development. Expert report.
6. Westside Resources, Inc.; Starz, Inc.; Tiplutions, Inc.; World Vision for Mankind; and Starz Westside Holdings, Inc. v. Crystal Tips Holdings, Inc. JAMS Arbitration, Case No. 1200057280. Evaluation of breach of contract and business impact related to dentistry medical devices. Expert analysis, deposition, arbitration testimony.
7. Fresenius Kabi USA, LLC v. Custopharm, Inc., United States District Court, Western District of Texas (Waco Division), Case No. 6:21-cv-00286-ADA. Evaluation of irreparable harm, balance of hardships, and public interest related to patent infringement and the treatment of myxedema coma and hypothyroidism. Expert declarations (x2).



8. Syngenta Crop Protection, LLC v. Atticus, LLC, United States District Court, District of North Carolina Western Division, Case No. 5-19-cv-00509. Evaluation of patent infringement, economic damages, reasonable royalty, and commercial success related to agricultural chemicals. Expert reports (x2), deposition.
9. Rebecca Holland New v. Thermo Fisher Scientific, Inc., United States District Court, North Carolina Middle District, Case No. 1:19-cv-00807-TDS-LPA. Evaluation of economic damages due to alleged discrimination, harassment, hostile and abusive working environment, retaliation, breach of contract, conversion, fraud, and failure to pay wages and benefits. Expert reports (x2).
10. Brian C. Williams, et al. v. The Estates LLC, et al., United States District Court, Middle District of North Carolina, Case No. 1:19-cv-00176-CCE-JLW. Evaluation of class certification and antitrust claims related to bid rigging and real estate foreclosures. Expert report.
11. In the Matter of Certain Non-Invasive Aesthetic Body-Contouring Devices, Components Thereof, and Methods of Using Same (BTL Industries, Inc., et al. v. Allergan, Inc. et al.), United States International Trade Commission, Investigation No. 337-TA-1219. Evaluation of domestic industry, commercial success, bond, and remedy related to body contour products. Expert report, deposition, trial testimony.
12. Boehringer Ingelheim Pharmaceuticals Inc., Boehringer Ingelheim International GmbH, Boehringer Ingelheim Corporation v. MSN Laboratories Private Ltd., MSN Pharmaceuticals, Inc., Sun Pharmaceutical Industries, Ltd., Sun Pharmaceutical Industries, Inc., Lupin Limited, Lupin Pharmaceuticals Inc., Dr. Reddy's Laboratories Ltd., Dr. Reddy's Laboratories, Inc., Cipla Limited, Cipla USA, and InvaGen Pharmaceuticals, Inc., Mankind Pharma Ltd., Lifestar Pharma LLC, Alkem Laboratories Ltd., Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., Laurus Labs Ltd., Laurus Generics Inc., Alembic Pharmaceuticals Ltd., Alembic Pharmaceuticals, Inc., Zydus Pharmaceuticals (USA) Inc., Cadila Healthcare Limited, Aizant Drug Research Solutions Pvt. Ltd., Princeton Pharmaceutical Inc., United States District Court, District of Delaware, Case No. 18-cv-01689-CFC. Evaluation of commercial success related to Jardiance, Glyxami, Synjardy, and Synjardy XR (empagliflozin) for the treatment of Type 2 diabetes. Expert report, deposition.
13. Wash World, Inc. v. Belanger, Inc. and Piston OPW, Inc. d/b/a OPW Inc., United States District Court, Eastern District of Wisconsin, Green Bay Division, Case No.



- EDWI-1-19-cv-01562. Evaluation of lost profits and reasonable royalty related to mechanical car wash systems. Expert report, deposition.
14. Arbor Global Strategies, LLC v. Samsung Electronics Co., Ltd., Samsung Electronics America, Inc., and Samsung Semiconductor, Inc., United States District Court, Eastern District of Texas, Marshall Division, Case No. EDTX-2-19-cv-00333. Evaluation of reasonable royalty related to semiconductors, integrated circuits, and electronics hardware. Expert report, deposition.
 15. Finjan, LLC v. Qualys, Inc., United States District Court, Northern District of California, Case No. 4:18-cv-07229-YGT. Evaluation of reasonable royalty related to cybersecurity software. Expert report, deposition.
 16. In the Inter Partes Review of U.S. Patent Nos. 8,257,723 and 7,744,913 (Palette Life Sciences, Inc. v. Incept LLC), United States Patent and Trademark Office, Patent Trial and Appeal Board, IPR2020-00002, IPR2020-00004. Evaluation of commercial success related to spacer technology for prostate cancer treatment. Expert declaration, deposition.
 17. SmileDirectClub, LLC v. Candid Care Co., United States District Court, District of Delaware, Case No. 20-cv-00583-CFC. Evaluation of irreparable harm, balance of hardships, and public interest related to dental alignment. Expert declaration.
 18. Finjan, LLC v. SonicWall, Inc., United States District Court, Northern District of California, Case No. 5:17-cv-04467-BLF. Evaluation of reasonable royalty related to cybersecurity software. Expert report, deposition.
 19. Vanda Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc., Apotex Inc., Apotex Corp., MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, United States District Court, District of Delaware, Case Nos. 1:18-cv-00651, 1:18-cv-00689, and 1:18-cv-000690. Evaluation of commercial success related to Hetlioz (tasimelteon) for the treatment of Non-24 sleep disorders. Expert report.
 20. Pharmacyclics LLC and Janssen Biotech, Inc. v. Zydus Worldwide DMCC, et al., Pharmacyclics LLC and Janssen Biotech, Inc. v. Alvogen Pine Books LLC and Natco Pharma LTD, United States District Court, District of Delaware, Case Nos. 1-18-cv-00192 (CFC), 1-19-cv-00434 (CFC)(CJB). Evaluation of commercial success related to Imbruvica (ibrutinib) to treat non-Hodgkin's lymphoma. Expert report, deposition, trial testimony.



21. In the Inter Partes Review of U.S. Patent Nos. 8,993,300, 8,455,232, 7,312,063, 7,829,318, 6,451,572, and 7,026,150 (Associated British Foods PLC, AB Vista, Inc., PGP International Inc., Abitec Corporation, AB Enzymes, Inc., and AB Enzymes GMBH v. Cornell Research Foundation, Inc.), United States Patent and Trademark Office, Patent Trial and Appeal Board, IPR2019-00577, IPR2019-00578, IPR2019-00579, IPR2019-00580, IPR2019-00581, IPR2019-00582. Evaluation of commercial success related to OptiPhos and Quantum products related to animal feed enzymes. Expert declaration.
22. Sonrai Systems, LLC v. Anthony M. Romano, Geotab, Inc., The Heil Co. d/b/a Environmental Solutions Group, and Alliance Wireless Technologies, Inc., United States District Court, Northern District of Illinois, Eastern Division, Case No. 16-cv-03371. Evaluation of trade secret misappropriation, interference with contracts, unfair competition, breach of contract, and other issues related to automobile telematics. Expert report, deposition.
23. Wirtgen America, Inc. v. United States of America, Department of Homeland Security, U.S. Customs and Border Protection, et al., United States District Court, District of Columbia, Case No. 20-cv-00195-CRC. Evaluation of competition and irreparable harm related to the importation of road milling machines. Expert declaration, hearing testimony.
24. In the Inter Partes Review of U.S. Patent 8,679,069 (Pfizer Inc. v. Sanofi-Aventis Deutschland GMBH), United States Patent and Trademark Office, Patent Trial and Appeal Board, IPR2018-00979. Evaluation of commercial success related to Lantus SoloStar (insulin glargine) for the treatment of diabetes. Expert declaration.
25. Vifor Fresenius Medical Care Renal Pharma Ltd., Vifor Fresenius Medical Care Renal Pharma France S.A.S. v. Lupin Atlantis Holdings SA, Lupin Pharmaceuticals, Inc., and Teva Pharmaceuticals USA, Inc., United States District Court, District of Delaware, Case No. 1:18-cv-00390-MN. Evaluation of commercial success related to Velphoro (sucroferric oxyhydroxide) for the treatment of chronic kidney disease and hyperphosphatemia. Expert report, deposition, trial testimony.
26. Impax Laboratories, Inc. v. Zydus Pharmaceuticals (USA) Inc., United States District Court, District of New Jersey, Case No. 2:17-cv-13476. Evaluation of commercial success related to Rytary (carbidopa and levodopa) for the treatment of Parkinson's disease. Expert report, deposition.
27. Mitsubishi Tanabe Pharma Corporation, Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica NV, Janssen Research and Development, LLC, and Cilag GmbH



- International v. Sandoz Inc. and Zydus Pharmaceuticals (USA) Inc., United States District Court, District of New Jersey, Case Nos. 17-05319, 17-06375, 17-12082, 18-06112. Evaluation of commercial success related to Invokana, Invokamet, and Invokamet XR (canagliflozin) for the treatment of Type 2 diabetes. Expert report, deposition, trial testimony.
28. Sanofi-Aventis US LLC, Sanofi-Aventis Deutschland GMBH, and Sanofi Winthrop Industrie, Biocon Limited, Biocon Research Ltd., Biocon S.A., Biocon Sdn. Bhd. v. Mylan GMBH, Mylan Inc., Mylan NV, And Mylan Pharmaceuticals Inc., United States District Court, District of New Jersey, Case No. 17-cv-09105-SRC-CLW. Evaluation of commercial success related to Lantus Vial and Lantus SoloStar (insulin glargine) for the treatment of diabetes. Expert report, deposition, trial testimony.
 29. In the Inter Partes Review of U.S. Patent 8,679,069; 8,992,486; 9,526,844; 9,604,008; 8,992,486 (Mylan Pharmaceuticals Inc. and Pfizer Inc. v. Sanofi-Aventis Deutschland GMBH), United States Patent and Trademark Office, Patent Trial and Appeal Board, IPR2018-01670, IPR2018-01678, IPR2018-01680, IPR2018-01682, IPR2018-01684, IPR2019-00122. Evaluation of commercial success related to Lantus SoloStar (insulin glargine) for the treatment of diabetes. Expert declaration, deposition.
 30. Align Technology, Inc. v. Strauss Diamond Instruments, Inc., United States District Court, Northern District of California, Case No. 18-cv-06663-TSH. Evaluation of trademark infringement, false advertising, unfair competition, and other claims related to dental imaging products. Expert report.
 31. L.A. International Corp., Manhattan Wholesalers Inc., Excel Wholesale Distributors Inc., Value Distributor, Inc., Border Cash & Carry, Inc., AKR Corporation, U.S. Wholesale Outlet & Distribution, Inc.; Sanoor, Inc. (D/B/A L.A. Top Distributor); Pittsburg Wholesale Grocers, Inc.; And Pacific Groservice, Inc. v. Prestige Brands Holdings, Inc. And Medtech Products Inc. United States District Court, Central District of California, Case No. 18-cv-06809-MWF-MRW. Evaluation of restitution and antitrust damages related to price discrimination for consumer health care products. Expert report, deposition, trial testimony.
 32. ON Semiconductor Corporation, Semiconductor Components Industries, LLC d/b/a ON Semiconductor. v. Power Integrations, Inc. United States District Court, Northern District of California, San Jose Division, Case Nos. 17-cv-03189-BLF, 16-cv-06371-BLF. Evaluation of patent infringement including reasonable royalty



- damages related to electronics and semiconductor products. Expert report, deposition.
33. Bristol-Myers Squibb Company and Pfizer Inc. v. Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd., Sigmapharm Laboratories, LLC, Unichem Laboratories, Ltd., and Zydus Pharmaceuticals (USA), Inc. United States District Court, District of Delaware, Case No. 17-cv-00374. Evaluation of secondary considerations related to Eliquis (apixaban) for the treatment of deep vein thrombosis, pulmonary embolism, and stroke prevention in nonvalvular atrial fibrillation. Expert report, deposition.
 34. Millennium Pharmaceuticals, Inc. v. Apotex Corp., Apotex, Inc., Hospira, Inc., Zydus Pharmaceuticals (USA) Inc., Cadila Healthcare Ltd. United States District Court, District of Delaware, Case No. 13-cv-01874. Evaluation of secondary considerations related to Velcade (bortezomib) for the treatment of multiple myeloma and mantle cell lymphoma. Expert report, deposition.
 35. US Wholesale Outlet & Distribution, Inc., Trepco Imports & Distribution, Ltd., L.A. International Corporation, California Wholesale, YNY International Inc., Eashou, Inc. dba San Diego Cash and Carry, Sanoor, Inc. dba L.A. Top Distributor v. Living Essentials, LLC and Innovation Ventures, LLC. United States District Court, Central District of California, Case No. 2:18-cv-1077. Evaluation of restitution and antitrust damages related to price discrimination for food and beverage products. Expert report, deposition.
 36. Allergan Sales, LLC; Forest Laboratories Holdings, Ltd.; Allergan USA, Inc.; and Ironwood Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc. and Sandoz Inc. United States District Court, District of Delaware, Case No. 16-1114-RGA. Evaluation of secondary considerations including commercial success, long-felt need, skepticism, and copying related to Linzess (linaclotide) for the treatment of irritable bowel syndrome. Expert report, deposition.
 37. Stayma Consulting Services, LLC v. Teligent, Inc. American Arbitration Association. Evaluation of trade secrets, breach of contract, unfair competition, and business harm related to pharmaceuticals products. Expert reports (x2).
 38. Orexo AB and Orexo US, Inc. v. Actavis Elizabeth LLC, Actavis Pharma, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries, Ltd. United States District Court, District of Delaware, Case No. 17-00205-CFC. Evaluation of patent infringement including reasonable royalty related to pharmaceuticals. Expert report, deposition, trial testimony.



39. Sumitomo Dainippon Pharma Co., Ltd. and Sunovion Pharmaceuticals Inc. v. Emcure Pharmaceuticals Ltd., Aurobindo Pharma Ltd., Dr. Reddy's Laboratories, Ltd., Dr. Reddy's Laboratories, Inc., Lupin Ltd., Sun Pharma Global Fze, Accord Healthcare Inc., Amneal Pharmaceuticals, LLC, Invagen Pharmaceuticals, Inc., Torrent Pharmaceuticals Ltd., Zydus Pharmaceuticals (USA) Inc. United States District Court, Central District of California, Case No. 2:18-cv-02065-SRC-CLW, 2:18-cv-02620-SRC-CLW. Evaluation of commercial success related to Latuda (lurasidone) for the treatment of schizophrenia and bipolar disorders. Expert report, deposition.
40. Carl Zeiss AG & ASML Netherlands B.V. v. Nikon Corporation, Sendai Nikon Corporation, and Nikon Inc. United States District Court, Central District of California, Case No. 2:17-cv-07083-RGK-MRW. Evaluation of patent infringement including reasonable royalty related to digital cameras. Expert report, deposition, trial testimony.
41. In the Inter Partes Review of U.S. Patent 7,476,652 and 7,713,930 (Mylan Pharmaceuticals Inc., v. Sanofi-Aventis Deutschland GMBH), United States Patent and Trademark Office, Patent Trial and Appeal Board, IPR2017-01526 and IPR2017-01528. Evaluation of commercial success related to Lantus Vial (insulin glargine) for the treatment of diabetes. Expert declaration, deposition.
42. Carl Zeiss AG & ASML Netherlands B.V. v. Nikon Corporation, Sendai Nikon Corporation, and Nikon Inc. United States District Court, Central District of California, Case No. 2:17-cv-03221-RGK-MRW. Evaluation of patent infringement including reasonable royalty related to digital cameras. Expert report, deposition, trial testimony.
43. Merck Sharp & Dohme Corp., Cubist Pharmaceuticals LLC, Optimer Pharmaceuticals LLC MSD Investment Holdings (Ireland), and MSD International GMBH v. Actavis Laboratories Fl, Inc., Actavis Pharma, Inc., and Actavis Inc. United States District Court of New Jersey, Case No. 2:15-cv-06541-WHW-CLW. Evaluation of commercial success of Difucid (fidaxomicin) for the treatment of Clostridium difficile-associated diarrhea. Expert report.
44. Gilead Sciences, Inc. v. Mylan Pharmaceuticals Inc. United States District Court of Delaware, Case No. 16-cv-00192-RGA. Evaluation of commercial success related to Tybost, Evotaz, Prezcobix, Stribild, and Genvoya for the treatment of HIV. Expert report, deposition.



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45. Immunex Corporation, Amgen Manufacturing, Limited, and Hoffmann-LA Roche Inc., v. Sandoz Inc., Sandoz International GMBH, and Sandoz GMBH. United States District Court of New Jersey, Case No. 2:16-cv-01118-CCC-MF. Evaluation of indications for and commercial success of Enbrel (etanercept) for the treatment of rheumatoid arthritis, psoriasis, and other indications. Expert reports (x2), deposition, trial testimony.

Robert B. Perni, Ph.D.

RBP

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PHARMACEUTICAL RESEARCH EXECUTIVE

Organic/medicinal chemist with 34 years medicinal chemistry/drug design and 30 years project leadership/research management experience. Research team leader and co-inventor of nine development candidates including Incivek™ (telaprevir, VX-950), a hepatitis C protease inhibitor approved in 2011.

PROFESSIONAL EXPERIENCE

IM Therapeutics, Woburn MA

2019-Present

Vice President, R&D

- Member of Executive Management Team
- Responsible for Drug Discovery activities including medicinal chemistry, computational chemistry
- Responsible for Process development and manufacturing of drug candidates

JMD Pharma Creativity, LLC, Marlborough, MA

2014-Present

Principal (2014-Present)

- Providing Medicinal Chemistry and Drug Discovery consulting services primarily for start-up and small biotechnology companies.

NiDares, Inc., Marlborough, MA

2013-2015

Co-founder and Director (2013-2015)

Sirtris Pharmaceuticals, Cambridge, MA

2007-2013

Vice President, Chemistry (2008-2013)

Senior Director, Chemistry (2007-2008)

- Member of Sirtris Executive Management Team
- Responsibility for medicinal chemistry research, synthetic chemistry, biophysics and compound management.
- Oversight over the identification of three SIRT 1 activator development candidates
- Oversight of extensive chemistry outsourcing operations
- Interim Head of Lead Discovery (Biochemistry/Enzymology) and Structural Biology (2008-2009)
- Management of >\$5MM annual Chemistry budget (operating and capital)

Robert B. Perni, Ph.D.

Vertex Pharmaceuticals, Cambridge, MA

1998-2007

Head, Outsource Chemistry Research (2006-2007)

- Managed outsourcing of medicinal chemistry activities including identifying vendors, setting up new collaborations and managing external chemistry FTEs.
- Strategic development and expansion of outsourcing capabilities.
- Advisor to all medicinal chemistry project teams.

Head, Hits to Leads Chemistry (2004-2006)

- Implemented new global Hits to Leads (HTL) effort providing HTL support to all sites (Cambridge, MA, San Diego, CA, Oxford, UK)
- Responsible for the design and strategic implementation of HTL, including developing innovative approaches/technologies for scaffold exploration, diversification and analysis

Project Head, Hepatitis C Protease Inhibition (1998-2005)

- Responsible for overseeing all aspects of the Hepatitis C NS3•4A Protease Inhibition Research Program. (1998-2005)
- Provided scientific direction and integration of multidisciplinary team.
- Managed \$2MM external annual budget and all program resources
 - Led team to the discovery of **Incivek™** (telaprevir, VX-950), a HCV protease inhibitor development candidate. Optimized 12 μ M lead to 7 nM selective inhibitor. (2001)
 - Led team to the discovery to a back-up development compound for VX-950 (2003)
- Head of Hepatitis C Protease Medicinal Chemistry group (1998-2005)
- Research Representative on HCV VX-950 Development Team (2001-2007)
- Research Representative on HCV In-licensing Team (2003-2005)
- Provided Business Development support in partnering activities in Hepatitis C R&D. (2003-2005)
- Responsible for managing collaborative efforts with Eli Lilly & Co (1998-2002)

Group Leader (1998)

- Responsible for leading HCV Medicinal Chemistry team.

Avid Therapeutics Philadelphia, PA

1995-1997

Director of Chemistry

- Responsible for all Chemical Research and Development
- Initiated Medicinal Chemistry efforts at Avid including hiring staff, renovating and setting up laboratory.
- Discovered novel series of compounds that inhibit replication of Hepatitis B virus: lead compound **AT-130**.
- Responsible for identifying and purchasing diverse compound collections for screening.

Robert B. Perni, Ph.D.

- Responsible for process/synthesis, formulation and all related issues of the HIV Protease Inhibitor DMP-450 for clinical trials.
- Responsible for all CMC documentation (IND) for DMP-450.
- Designed and assembled Company chemical databases.
- Worked with collaborators at Parke-Davis on HBV program, though all chemistry performed at Avid.
- Provided Business Development support in partnering activities in Hepatitis B R&D.

Sterling Winthrop, Inc. Rensselaer, NY and Collegeville, PA

1986-1994

Senior Research Investigator (1990-1994)

- Project Leader, Bioreductive Radiosensitizer Collaboration with Stanford University and SRI International (1992-1994) Responsible for overseeing all scientific aspects of research carried out at SRI (medicinal chemistry) and Stanford University (biological evaluation).
 - Efforts resulted in the clinical development of **tirapazamine (WIN 59075)**.
- Project Chemist for Cytotoxic Screening Project (1990-1994). Responsible for structural assessment of hits and subsequent analog design and synthesis.
 - Efforts resulted in the advancement of anti-tumor agent **WIN 33377** into Phase 2 clinical development and the identification of a backup compound, **WIN 68210**.
 - A 2nd generation solid tumor selective agent, **SR271425** was also identified and subsequently entered clinical development.

Research Investigator (1988-1990)

- Project Chemist for Bioreductive Radiosensitizer Collaboration (1989-1992). Responsible for overseeing drug design and synthesis carried out at SRI International.
- Design and synthesis of compounds for the antiviral and cardiovascular programs (1988-1990).
- Chairman Medicinal Chemistry Colloquium Program (1988-1990).

Senior Research Chemist (1986-1988)

- Design and synthesis of novel antibacterial (quinolone gyrase inhibitors) and antiviral agents (quinolone-based antiherpetics)

ACADEMIC EXPERIENCE

University of Rochester – Postdoctoral Fellow (1984-1986) Advisor: Prof. Robert K. Boeckman, Jr.

- Research directed toward the total synthesis of the macrocyclic antibiotic Ikarugamycin.

Dartmouth College – Postdoctoral Fellow (1984) Advisor: Prof. Gordon W. Gribble

- Research directed toward the synthesis of polycyclic aromatic hydrocarbons.

Dartmouth College – PhD Organic Chemistry (1979-1983) Advisor: Prof. Gordon W. Gribble

Robert B. Perni, Ph.D.

- Doctoral Dissertation: “Conventional and Biomimetic Synthetic Entries to *Aristotelia* Alkaloids”

Northeastern University – BS Chemistry (1974-1979) Advisor: Dr. Bill C. Giessen

- Undergraduate research on the preparation and characterization of novel amorphous alloys.

Harvard School of Public Health, Cooperative Education Program with Northeastern Univ. (1976-1978)

- Developed and applied analytical methods to environmental problems.

PERSONAL

Professional Affiliations and Activities

- Scientific Advisory Board Member, CreaGen BioSciences (2018-present)
- Scientific Advisory Board Member, WntRx Pharmaceuticals (2016-Present)
- Mentor, MassCONNECT Program (a mentoring program of Mass Bio) (2014-present)
- Advisory Board Member, Barnett Institute (Northeastern University) (2012-present)
- Member of the American Chemical Society (1979-present)
- Reviewer for the following Journals:
 - Journal of Organic Chemistry
 - Journal of Medicinal Chemistry
 - Bioorganic and Medicinal Chemistry Letters
 - Bioorganic and Medicinal Chemistry
 - Nature, Chemical Biology
 - Expert Opinion on Investigational Drugs
 - Antiviral Agents and Chemotherapy
 - Virology Journal
 - Tetrahedron Letters

Awards and Recognition

- Recipient of the *Bioorganic and Medicinal Chemistry Letters* Most Cited Paper Award 2003-2006
- Cited by Boston Business Journal as “Champions in Healthcare: Innovator, 2004”
- Recipient of 3 Sterling Winthrop Vision and Accomplishment Awards 1992-1994

Publications

Approximately 175 publications including research papers, abstracts/presentations, review articles and patents.

Languages

Fluent in Italian, reading comprehension of German and Spanish

REFERENCES: Provided on request

PUBLICATIONS

RESEARCH MANUSCRIPTS

1. "Synthesis of New Pyrrolo[3,4-b]indol-3-ones as Latent Substrates for Pyrrolo[3,4-b]indoles" Saulnier, M.G.; Schreiber, S.M.; Cavanaugh, K.L.; Perni, R.B.; Joyner, H.H.; Gribble*, G.W. *ARKIVOC* **2021**, 15-23.
2. "A Synthetic Approach to (+) Aristomakine" Perni, R.B.; Gribble, G.W. *ARKIVOC* **2018**, 75-84.
3. "Crystallographic structure of a small molecule SIRT1 activator-enzyme complex" Dai, H.; Case, A.W, Riera, T.V.; Considine, T.; Lee, J.; Hamuro, Y.; Zhao, H.; Jiang, Y.; Sweitzer, S.M.; Pietrak, B.; Schwartz, B.; Blum, C.A.; Disch, J.S.; Caldwell, R.; Szczepankiewicz, B.; Oalman, C.; Ng, P.Y.; White, B.H.; Casaubon, R.; Narayan, R.; Koppetsch, K.; Bourbonais, F.; Wu, B.; Wang, J.; Qian, D.; Jiang, F.; Mao, C.; Wang, M.; Hu, E.; Wu, J.C.; Perni, R.B.; Vlasuk, G.P.; Ellis, J.L. *Nature Commun.* **2015**, DOI: 10.1038/ncomms8645
4. "The Identification of the SIRT1 Activator SRT2104 as a Clinical Candidate" Ng, P.Y.; Bemis, J.E.; Disch, J.S.; Vu, C.B.; Oalman, C.J.; Lynch, A.V.; Carney, D.P.; Riera, T.V.; Song, J.; Smith, J.J.; Lavu, S.; Tornblom, A.; Duncan, M.; Yeager, M.; Kriksiukaite, K.; Gupta, A.; Suri, V.; Elliot, P.J.; Milne, J.C.; Nunes, J.J.; Jirousek, M.R.; Vlasuk, G.P.; Ellis, J.L.; Perni, R.P. *Lett. Drug Des. Disc.* **2013**, 10, 793-797.
5. "The Synthesis of Halomethyltrifluoroborates Through Continuous Flow Chemistry" Broom, T.; Hughes, M.; Szczepankiewicz, B.G.; Ace, K.; Hagger, B.; Lacking, G.; Chima, R.; Marchbank, G.; Alford, G.; Evans, P.; Cunningham, C.; Robert, J.C.; Perni, R.B.; Berry, M. Rutter, A.; Watson, S.A. *Org. Proc. Res. Dev.* **2014**, 18, 1354-1359.
6. "Discovery of Thieno[3,2-d]pyrimidine-6-carboxamides as potent inhibitors of SIRT1, SIRT2 and SIRT3" Disch, J.S.; Evindar, G.; Chiu, C.H.; Blum, C.A.; Dai, H.; Jin, L.; Schuman, E.; Lind, K.E.; Belyanskaya, S.L.; Cuozzo, J.W.; Vlasuk, G.P.; Mao, C.; Perni, R. B. *J. Med. Chem.* **2013**, 56, 3666-3679.
7. "Evidence for a Common Mechanism of SIRT1 Regulation by Allosteric Activators" Hubbard, B.P.; Gomes, A, P.; Dai, H.; Li, J.; Case, A.W.; Considine, T.; Riera, T.V.; Lee, J.E.; E, S.Y.; Lamming, D.W.; Pentelute, B.L.; Schuman, E.R.; Stevens, L.A.; Ling, A.J.Y.; Armour, S.M.; Michan, S.; Zhao, H.; Jiang, Y.; Sweitzer, S.M.; Blum, C.A.; Disch, J.S.; Ng, P.Y.; Howitz, K.T.; Rolo, A.P.; Hamuro, Y.; Moss, J.; Perni, R.B.; Ellis, J.L.; Vlasuk, G.P.; Sinclair, D.A. *Science* **2013**, 339, 1216- 1219.
8. "Synthesis of Carba-NAD and the Structures of Its Ternary Complexes with SIRT3 and SIRT5" Szczepankiewicz, B.G.; Dai, H.; Koppetsch, K.J.; Qian, D.; Jiang, F.; Mao, C.; Perni, R.B. *J. Org. Chem.* **2012**, 77, 7319-7329.
9. "One-Step, Non-enzymatic Synthesis of O-Acetyl-ADP-ribose and Analogues from NAD and Carboxylates" Szczepankiewicz, B.G.; Koppetsch, K.J.; Perni, R.B. *J. Org. Chem.* **2011**, 76, 6465-6474.
10. "SIRT1 Activation by Small Molecules-Kinetic and Biophysical Evidence for Direct Interaction of Enzyme Activator" Dai, H.; Kustigian, L.; Carney, D.; Case, A.; Considine, T.; Hubbard, B.; Perni, R.B.; Riera, T.V.; Szczepankiewicz, B.; Vlasuk, G.P.; Stein, R.L. *J. Biological Chem.* **2010**, 285, 32695-32703.
11. "In vitro and in vivo Isotope Effects with Hepatitis C Protease Inhibitors: Enhanced Plasma Exposure of Deuterated-telaprevir vs. Telaprevir in Rats" Maltais, F.; Jung, Y.C.; Chen, M.; Tanoury, J.; Perni, R.B.; Mani, N.; Laitinen, L.; Huang, H.; Liao, S.; Tsao, H.; Block, E.; Ma, C.; Shawgo, R.S.; Town, C.; Brummel, C.L.; Howe, D.; Pazhanisamy, S.; Raybuck, S.; Namchuck, M.; and Bennani, Y. *J. Med. Chem.* **2009**, 52, 7993-8001.

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12. "Crystal Structures of Human SIRT3 Displaying Substrate-induced Conformational Changes" Jin, L.; Wei, W.; Jiang, Y.; Peng, H.; Cai, J.; Mao, C.; Dai, H.; Choy, W.; Bemis, J.E.; Jirousek, M.R.; Milne, J.C.; Westphal, C.H.; Perni, R.B. *J. Biol. Chem.* **2009**, *284*, 24394-24405.
13. "Discovery of Oxazolo[4,5-b]pyridines and Related Heterocyclic Analogs as Novel SIRT1 Activators" Bemis, J.E.; Vu, C.B.; Xie, R.; Nunes, J.J.; Ng, P.Y.; Disch, J.S.; Milne, J.C.; Carney, D.P.; Lynch, A.V.; Jin, L.; Smith, J.J.; Lavu, S.; Iffland, A.; Jirousek, M.J.; Perni, R.B.; *Bioorg. Med. Chem. Lett.* **2009**, *19*, 2350-2353.
14. "Discovery of Benzothiazole Derivatives as Efficacious and Enterocyte-Specific MTP Inhibitors" Vu, C.B.; Milne, J.C.; Carney, D.P.; Song, J.; Choy, W.; Lambert, P.D.; Gagne, D.J.; Hirsch, M.; Cote, A.; Davis, M.; Lainez, E.; Meade, N.; Normington, K.; Jirousek, M.R.; Perni, R.B. *Bioorg. Med. Chem. Lett.* **2009** *19*, 1416-1420.
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165. "The Importance of Medicinal Chemistry in Drug Discovery" Round Table Moderator, MASS BIO CRO/CMO Symposium, Boston MA Nov. **2015**.
166. "Smart Sourcing Versus Outsourcing" Biotech Tuesday Panel Discussion, Cambridge, MA June, **2013**
167. "Drug Discovery at Sirtris" Drug Discovery Committee, Mass Biotech Council Meeting, Cambridge, MA September, **2009**
168. "The Design of HCV NS3•4A Protease Inhibitors Leading to the Discovery of VX-950" Drew University, Residential School on Medicinal Chemistry, Madison, NJ, June **2006**.
169. "The Design of Hepatitis C Protease inhibitors and the Discovery of VX-950" 37th Great Lakes Regional Meeting of the American Chemical Society, Milwaukee, WI, June **2006**.
170. "Designing an Inhibitor of a Recalcitrant Enzyme: The Tale of VX-950 and the HCV NS3•4A Protease" ACS ProSpectives, Discovery and Selection of Successful Drug Candidates. Cambridge, MA, May **2006**.

Robert B. Perni, Ph.D.

171. "The Discovery of VX-950, an Inhibitor of the HCV NS3•4A Protease in Clinical Development" Gordon Research Conference on Medicinal Chemistry, New London, NH, August **2005**.
172. "The Design of VX-950, an Inhibitor of the HCV NS3•4A Protease with Potent *in vitro and in vivo* Activities" ScreenTech 2004, Protease Symposium, San Diego, CA, March **2004**.
173. "NS3•4A Protease Inhibition: A New Therapy for Hepatitis C Infection" Grand Rounds, Eli Lilly & Co. Indianapolis, IN, June **2001**.
174. "Ketoamide Synthesis" Synthetic Pathways Symposium Gainesville, FL, November **2000**.
175. "In Search of Better Inhibitors of the Hepatitis C NS3•4A Protease Domain" Symposium on Advances in Protease Inhibitors. ACS National Meeting Anaheim, CA, March **1999**.
176. "Anti-solid Tumor Agents" Department of Chemistry, Dartmouth College, Hanover, NH, April **1994**.
177. "Rational Drug Design: Synthesis of Novel Antibacterial Agents" Department of Chemistry, Middlebury College, Middlebury, VT, April **1988**.

Harvard Medical School Curriculum Vitae

Date Prepared: July 17, 2019

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Place of Birth: Philadelphia, PA

Education

09/74-06/78	BA	Psychobiology	Williams College, Williamstown, MA
09/79-06/83	PhD	Psychobiology (Robert McCarley MD PhD)	Harvard University, Cambridge, MA
09/83-06/87	MD	Medicine	Harvard Medical School

Postdoctoral Training

07/87-07/88	Intern	Internal Medicine	Mt. Zion Hospital and Medical Center, San Francisco, CA
07/88-07/90	Resident	Psychiatry	Massachusetts General Hospital
07/90-07/91	Chief Resident	Clinical Psychopharmacology Unit	Massachusetts General Hospital
07/91-07/92	Clinical Fellow	Neurology (Sleep Medicine)	Massachusetts General Hospital

Faculty Academic Appointments

1986-1987	Lecturer	Psychology	Harvard Graduate School of Arts and Sciences
1991-1996	Instructor	Psychiatry	Harvard Medical School
1996-2000	Instructor	Medicine	Harvard Medical School
2000-2007	Assistant Professor	Psychiatry	Harvard Medical School
2008-2017	Associate Professor	Psychiatry	Harvard Medical School
2017-	Professor	Psychiatry	Harvard Medical School

Appointments at Hospitals/Affiliated Institutions

07/91-07/99	Clinical Assistant	Psychiatry	Massachusetts General Hospital
07/91-07/00	Assistant Physician	Psychiatry	McLean Hospital, Belmont MA
07/96-	Associate Physician	Medicine	Brigham and Women's Hospital
07/06-	Psychiatrist	Psychiatry	Brigham and Women's Hospital
09/13-02/15	Associate Psychiatrist	Psychiatry	Massachusetts General Hospital
02/15-	Psychiatrist	Psychiatry	Massachusetts General Hospital

Other Professional Positions

1999-2005, 2006-2012, 2013-	Medical Advisory Board	Restless Legs Syndrome Foundation	1-4 days per year
2014-2017	Sleep Physiology and Insomnia Global Advisory Board	Merck	2 days per year
2015-2017	Scientific Advisory Board	FlexPharma	4 days per year

Major Administrative Leadership Positions**Local**

1986-1987	Course Director, <i>Psychobiology</i>	Harvard University Faculty of Arts and Sciences
1998-present	Course Co-Director, <i>Clinical Sleep Disorders</i> , 4 th	Harvard Medical School

	year elective	
1990-1991	Symposium Organizer, <i>Physiological Markers in Psychiatry</i> , Clinical Psychopharmacology Unit	Massachusetts General Hospital
1991-1996	Medical Director, Sleep Disorders Center and Sleep Research Program	McLean Hospital
1995-1996	Course Director, <i>Organic Mental Disorders</i> , PGY 2 Psychiatry and Neurology Residents	McLean Hospital
1996	Symposium Director, <i>Harvard Psychiatry Day</i> , All residents and child fellows in Harvard-affiliated psychiatry programs	Harvard Medical School
1996-2006	Associate Clinical Director, Sleep Disorders Service	Brigham and Women's Hospital
1997, 1999	Course Director, <i>Diagnosis and Treatment of Sleep Disorders</i>	Brigham and Women's Hospital
1999-2013	Medical Director, Sleep Health Center	Brigham and Women's Hospital, Newton/Brighton, MA
2001	Course Director, <i>Sleep Medicine: 2001</i>	Brigham and Women's Hospital
2002	Course Director, <i>Advances in Sleep Medicine</i>	Brigham and Women's Hospital
2008	Symposium organizer, <i>Update on Diagnosis and Pathophysiology of Restless Legs Syndrome</i> , Division of Sleep Medicine	Harvard Medical School
2013-	Chief, Sleep Disorders Clinical Research Program, Department of Psychiatry	Massachusetts General Hospital
<u>International</u>		
2005	Chair, Scientific Committee, <i>Fourth International Scientific Symposium on Parkinson's Disease and Restless Legs Syndrome</i>	Stressa, Italy (Boehringer-Ingelheim)

Committee Service

Local

1989-1993	Psychiatry Residency Selection Committee	Massachusetts General Hospital
1989-1991	Psychiatry Residency Training Committee	Massachusetts General Hospital
1997	Mental Status Examination Committee for Medical School Psychiatric Education	Harvard Medical School
2005-2006	Consultant, Pharmacy and Therapeutics Committee	Partners Healthcare
2006-2012	Sleep Fellowship Selection Committee, Division of Sleep Medicine	Brigham and Women's Hospital
2014-	Associate Preceptor, Training Program in Sleep, Circadian, and Respiratory Neurobiology	Harvard Medical School
2016-	Benzodiazepine Task Force, Department of Psychiatry	Massachusetts General Hospital

2017-	Opioid Task Force, Department of Psychiatry	Massachusetts General Hospital
2018-	Faculty Executive Committee	Harvard Medical School, Division of Sleep Medicine

Regional

2003-2005	Psychopharmacology Work Group	Commonwealth of Massachusetts, Dept. of Mental Health
2009-2010	Key Informant Panel, Sleep Apnea Diagnosis and Treatment	Tufts Evidence-based Practice Center, Agency for Healthcare Research and Quality, Boston, MA

Professional Societies

2004-2007	Chair, Nosology Committee	American Academy of Sleep Medicine
2006-2008	Chair, Movement Disorders and Parasomnias Section	American Academy of Sleep Medicine
2007-2016	Chair, Practice Parameter for the Treatment of Restless Legs Syndrome	American Academy of Neurology
2007-2010, 2010-2015	Executive Committee	International Restless Legs Syndrome Study Group
2011-2012	Member, Scoring Manual Committee	American Academy of Sleep Medicine
2014-2017	Member, Restless Legs Syndrome Evidence-Based Treatment Committee	Movement Disorders Society
2017-	Secretary, Executive Committee	International Restless Legs Syndrome Study Group
		International Restless Legs Syndrome Study Group

Editorial Activities

Ad hoc Reviewer

American Journal of Kidney Diseases
 American Journal of Medicine
 Annals of Neurology
 Archives of Internal Medicine
 British Medical Journal
 Clinical Neurophysiology
 CNS Drugs
 CNS Spectrums
 European Journal of Neurology
 Expert Opinion in Pharmacotherapy
 General Hospital Psychiatry
 Health and Quality of Life Outcomes

Human Brain Mapping
 International Journal of Sleep Disorders
 Journal of Alternative and Complementary Medicine
 Journal of the American Medical Association (JAMA)
 Journal of the American Society of Nephrology
 Journal of Attention Disorders
 Journal of Biological Rhythms
 Journal of Clinical Psychiatry
 Journal of Clinical Sleep Medicine
 Journal of Clinical Psychopharmacology
 Journal of Neurological Sciences
 Journal of Neurology, Neurosurgery and Psychiatry
 Journal of Perinatology
 Journal of Psychosomatic Research
 Journal of Sleep Research
 Journal Watch Neurology
 Lancet
 Lancet Neurology
 Medical Letter
 Movement Disorders
 Nature Genetics
 Neurology
 Neuropsychiatric Disease and Treatment
 New England Journal of Medicine (NEJM)
 PLOS ONE
 The Primary Care Companion for CNS Disorders
 Psychological Medicine
 Psychosomatic Medicine
 Psychosomatics
 Sleep
 Sleep Medicine
 Sleep Medicine Reviews
 Stroke
 Tremor and Other Hyperkinetic Disorders

Other Editorial Roles

1999	Advisor, text revision to DSM-IVR	American Psychiatric Association
2005-	Editorial Board Member	Sleep Medicine
2005-2007	Advisor, revision to scoring manual	American Academy of Sleep Medicine
2005-2007	Editorial Board Member	International Journal of Sleep and Wakefulness
2006-	Editorial Board Member	CNS Drugs
2006-2011	Editor	RLS Scientific Bulletin, Restless Legs Syndrome Foundation
2007-2016	Associate Editor	Sleep
2012	Advisor, DSM-5	American Psychiatric Association

2017-	Academic Editor	PLOS One
2018-	Associate Editor	Frontiers in Neuroscience: Sleep and Circadian Rhythms

Honors and Prizes

1978	Phi Beta Kappa, Sigma XI, Highest Honors in Psychology	Williams College
1979-1980	Tuition scholarship and teaching stipend	Harvard Graduate School
1980-1983	Tuition scholarship and teaching stipend	National Science Foundation
1989	Outstanding Resident Award	National Institute of Mental Health
2007	Movement Disorders Section Investigator Award	American Academy of Sleep Medicine
2011-2012	BRI Fund to Sustain Research Excellence	Biomedical Research Institute, Brigham and Women's Hospital

Report of Funded and Unfunded Projects

Funding Information

Past Funded Projects

1996-2001	Sleep Academic Award NHLBI#HL-96-006 (to BWH) Co-PI (with J. Woodrow Weiss MD) The major goal of the grant was to plan and institute methods for introduction of courses related to sleep medicine into the Harvard Medical School curriculum.
2000-2007	Circadian Rhythms of Neuropathic Pain Pfizer Inc. (to BWH) PI, Investigator Initiated, Total Costs: \$114,700 The major goal of the study was to use the forced desynchrony protocol to define the independent roles of circadian rhythms and homeostatic drive in diabetic peripheral neuropathy pain severity.
2003-2004	Randomized Double-Blind, Placebo-Controlled Dose-Response Study of the Efficacy and Safety of Sumanitrole in Patients with Idiopathic Restless Legs Syndrome Pharmacia, Phase II trial (to SHC) PI, Total Costs: \$144,699 The major goal of the study was to test the efficacy and safety of the dopamine agonist sumanitrole in the treatment of restless legs syndrome.
2003-2005	A Double-blind Crossover Trial of Levetiracetam (Keppra) and Placebo in the treatment of Restless Legs Syndrome

UCB Pharma (to SHC)

PI, Investigator initiated, Total Costs: \$362,500

The major goal of the study was to test the efficacy and safety of the levetiracetam in the treatment of restless legs syndrome.

2004-2005 A Randomized, Double-blind, Placebo- controlled, Parallel Group Clinical Trial Comparing Fixed Doses of 0.25 mg, 0.50 mg, and 0.75 mg Pramipexole (Mirapex) Administered Orally to Investigate the Safety and Efficacy in Patients with Idiopathic Restless Legs Syndrome for 12 weeks.

Boehringer Ingelheim Pharmaceuticals Inc., Phase III trial (to SHC)

PI, National Coordinating Investigator, Total Costs: \$55,984

The major goal of the study was to test the efficacy and safety of the dopamine agonist pramipexole in the treatment of restless legs syndrome.

2004-2005 A 12 week, Double-blind, Placebo-controlled, Twice Daily Dosing Study to Assess the Efficacy and Safety of Ropinirole in Patients Suffering from Restless Legs Syndrome Requiring Extended Treatment Coverage.

GlaxoSmithKline, Phase IV trial (to SHC)

PI, Total Costs: \$147,969

The major goal of the study was to test the efficacy and safety of the dopamine agonist ropinirole in the treatment of restless legs syndrome.

2005 A 12 Week, Double-blind, Placebo-controlled Study to Assess the Tolerability, Efficacy, and Safety of Ropinirole Dosed PRN in Subjects with Restless Legs Syndrome who Respond to Open-Label Treatment with Ropinirole

GlaxoSmithKline, Phase IV trial (to SHC)

PI, Total Costs: \$15,290

The major goal of the study was to test the efficacy and safety of the dopamine agonist ropinirole in the treatment of patients with intermittent restless legs syndrome.

2005-2006 A Multi-Center, Randomized, Double Blind, Placebo-Controlled, Five Arm Parallel Group Trial to Investigate the Efficacy and Safety of Four Different Transdermal Doses of Rotigotine in Subjects with Idiopathic Restless Legs Syndrome

Schwarz Biosciences, Phase II trial (to SHC)

PI, Total Costs: \$177,133

The major goal of the study was to test the efficacy and safety of the dopamine agonist rotigotine in the treatment of restless legs syndrome.

2006-2007 A 12-Week, Multi-Center, Double-blind, Placebo-Controlled, Parallel Group Flexible Dose Polysomnography Study of Ropinirole Controlled Release for Restless Legs Syndrome

GlaxoSmithKline, Phase II trial (to SHC)

PI, Total Costs: \$45,307

The major goal of the study was to test the efficacy, effects on polysomnography, and safety of the dopamine agonist ropinirole in the treatment of restless legs syndrome.

2006-2007 A Phase IV Randomized, Double-blind, Active and Placebo Controlled, 6 Week Trial to Investigate the Efficacy and Safety of a Starting (and Fixed) Dose of .25 mg

- Pramipexole (Mirapex) in Patients with Idiopathic Restless Legs Syndrome
Boehringer Ingelheim Pharmaceuticals, Phase IV trial (to SHC)
PI, National Coordinating Investigator, Total Costs: \$57,529
The major goal of the study was to test the efficacy and safety of the dopamine agonist pramipexole in the treatment of restless legs syndrome.
- 2005-2008 The Effects of Eszopiclone Treatment (3 mg for two months) to Counteract the Adverse Metabolic Consequences of Primary Insomnia
Sepracor (to BWH)
PI, Investigator Initiated, Total Costs: \$506,610
The major goal of the study was to test the relationship of two-month treatment response to eszopiclone or placebo to changes in glucose tolerance as assessed by IVGTT. The secondary aim was to test whether there were identifiable changes in brain transmitters and metabolites as assessed by magnetic resonance spectroscopy or in hippocampal morphology as assessed by MRI in patients with primary insomnia.
- 2009 - 2010 A Polysomnography Study of GSK 1838262 (XP13512) Extended Release Tablets Versus Placebo in the Treatment of Restless Legs Syndrome (RLS) and Associated Sleep Disturbance
GlaxoSmithKline (to SHC)
PI, Total Costs: \$290,392

The major goal of this study was to test the efficacy and safety of XP13512 in the treatment of restless legs syndrome
- 2011-2012 A Randomized, Double-blind, Placebo-controlled, Parallel Group Study to Determine the Safety and Efficacy of IPX 159 in the Treatment of Moderate to Severe Restless Legs Syndrome (RLS)
Impax Pharmaceuticals (to SHC)
PI, Total Costs: \$80,567
The major goal of the study was to test the efficacy and safety of IPX1159 in the treatment of Restless Legs Syndrome
- 2012-2013 A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Polysomnography Study to Investigate Safety and Efficacy of Rotigotine Transdermal Patch in Patients with Restless Legs Syndrome and End-Stage Renal Disease Requiring Hemodialysis
UCB Pharma (to SHC)
International Coordinating Investigator, PI, Total Costs: \$12,278
The major goal of the study was to test the efficacy and safety of rotigotine in the treatment of restless legs syndrome in ESRD
- 2012-2013 A Phase 3B, Double-Blind, Randomized, Placebo-Controlled Study of Rotigotine and its Effect on All-Day Functioning and Quality of Life in Subjects with Moderate to Severe Idiopathic Restless Legs Syndrome
UCB Pharma (to SHC)
PI, Total Costs: \$235,497
The major goal of the study was to test the efficacy and safety of rotigotine in the

treatment of restless legs syndrome

- 2009-2014 Thalamic and Anterior Cingulate Cortex GABA and Glutamate in Restless Legs Syndrome: A 1-HMRS study
GSK (to SHC)
PI, Investigator Initiated, Total Direct Costs: \$222,500
The major goal of this study is to determine if abnormalities exist in RLS in levels of the major inhibitory and excitatory neurotransmitters in key pain modulating pathways.
- 2013 Butrans for Treatment of Restless Legs Syndrome
Purdue (to MGH)
PI, Investigator initiated, Total Costs (terminated study): \$18,421
The major goal of the study was to test the efficacy and safety of butrans in the treatment of restless legs syndrome
- 2012-2015 Restless Legs Syndrome and Cardiovascular Control
UCB Pharma, (to BWH)
PI, Investigator initiated, Total Direct Costs: \$113, 050
The goal of this study is to determine if patients with restless legs syndrome exhibit autonomic dysfunction compared with age-matched health controls.
- 2014-2015 Efficacy of the SENSUS Pain Management System in the treatment of RLS: an open-label trial
Neurometrix, Inc., investigator initiated (to MGH)
PI, Total Direct Costs: \$56,935
The primary objective of this study is to determine whether the SENSUS device is an effective and safe treatment for RLS.
- 2014-2016 A method to switch from oral dopamine agonists to rotigotine in patients with restless legs syndrome
UCB Pharma, investigator initiated (to MGH)
PI, Total Direct Costs: \$186,401
The goal of this study is to determine the optimal algorithm for switching patients with restless legs syndrome from oral dopaminergic agents to transdermal rotigotine.
- 2015-2018 Relationship of changes in polysomnographic and subjective sleep measures to RLS clinical assessments using the IRLS, CGI and SIT in a trial of gabapentin enacarbil in patients with restless legs syndrome
Xenoport, investigator initiated
PI, Total Direct Costs: \$50,432
The goal of this study is a secondary analysis to assess whether sleep variables predict the clinical improvements in RLS in clinical trials
- 2012-2018 Cortical GABA in MDD and Primary Insomnia with Magnetic Resonance Spectroscopy
NIMH 1RO1MH095792-01A1 (to MGH)
PI, Total Direct Costs: \$1,557,081
The principal objective of this study is to evaluate regional neurochemical alterations in primary insomnia and MDD using 1H-MRS in order to determine whether GABA abnormalities in MDD are related to insomnia or the mood state.

- 2016-2018 A Double-Blind, Multi-Center, Randomized, Placebo-Controlled Study to Investigate the Efficacy and Safety of Injectafer® (Ferric Carboxymaltose) in the Treatment of Restless Legs Syndrome (RLS)
Luitpold Pharmaceuticals, Inc.
PI, Total Direct Costs: \$136,735
The primary objective of this study is to evaluate the efficacy and safety of intravenous Injectafer® in subjects with Restless Legs Syndrome (RLS).
- 2016-2018 Prospective Validation of Quell® Sleep/Wake Classification and Periodic Leg Movement Detection
Neurometrix
PI, Total Direct Costs: \$16,903
The primary objective of this study is to evaluate the accuracy of the Quell TENS device for recording and scoring periodic limb movements of sleep.

Past Unfunded Projects

- 2009-2011 A 1H-MRS Study of Altered Regional Brain GABA in Insomnia
PI, Investigator Initiated
The major goal of the study was to test whether there were identifiable changes in brain transmitters and metabolites as assessed by magnetic resonance spectroscopy or in voxel-based morphology/diffusion tensor imaging as assessed by MRI in patients with primary insomnia and major depressive disorder.

Current Funded projects

- 2017- Multi-center Longitudinal Pilot Observational Study of Efficacy and Tolerability of Long-term Treatment of Restless Legs Syndrome Using Opioids
Restless Legs Syndrome Foundation
PI, Total Direct Costs: \$144,532
The primary objective of this study is to evaluate the long-term efficacy and tolerability of opiate medications in the treatment of restless legs syndrome.
- 2019- Effect of Suvorexant on Sleep Disturbance in Patients with Chronic Insomnia and Suboptimally Controlled Type 2 Diabetes: A Randomized 3-month Clinical Trial Using a Sequential Parallel Comparison Design
Merck & Co., Inc.
PI, Total Direct Costs: \$374,251.20
The primary objective of this study is to determine the effect of suvorexant on subjective total sleep time (TST) in suboptimally controlled Type 2 diabetics with chronic insomnia.

Current Unfunded Projects

- 2008- A Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Determine the Efficacy and Safety of Topiramate in the Treatment of Sleep Related Eating Disorder (SRED)
PI, Investigator Initiated
The major goal of the study is to test the efficacy and safety of topiramate in the treatment

of sleep-related eating disorder.

Report of Local Teaching and Training

Teaching of Students in Courses

1986-1987	Psychobiology Harvard undergraduates	Harvard University, Faculty of Arts and Sciences, 18 lectures
1994-1999	Mental Status Examination 2 nd year medical students	Harvard Medical School 2 hrs contact/yr

Formal Teaching of Residents, Clinical Fellows and Research Fellows (post-docs)

No presentations below were sponsored by outside entities

1991-1995	Sleep Disorders Psychiatry residents	McLean Hospital One hour lecture
1996	Sleep Disorders Psychiatry residents	Brigham and Women's Hospital One hour lecture
1994	Sleep Disorders in Primary Care Primary Care residents	Massachusetts General Hospital One hour lecture
1996	Sleep Disorders Internal Medicine residents	Brigham and Women's Hospital One hour lecture
1996-	Psychiatric Aspects of Sleep Disorders Psychiatry residents, Medical psychiatry fellows	Harvard-Longwood Psychiatry Residency
1997	Sleep Disorders in Women Internal Medicine residents	Brigham and Women's Hospital One hour lecture
1997-2005	Insomnia in Primary Care Primary Care residents	Brigham and Women's Hospital One hour lecture
1997	Sleep Disorders and Chronic Pain Pain fellows	Brigham and Women's Hospital One hour lecture
1998-2007	Neuropsychiatry of Sleep Disorders Psychiatry residents	Massachusetts General Hospital/McLean hospital Psychiatry Residency One hour lecture
1998-2007	Psychopharmacology of Sleep Disorders Psychiatry residents	Massachusetts General Hospital One hour lecture

2003-2005	Insomnia Neurology fellows	Brigham and Women's Hospital One hour lecture
2003-2013	Psychiatric Medications and Illness: Effects on Sleep; Sleep related Movement Disorders, Psychopharmacology of Insomnia BWH Sleep fellows	Brigham and Women's Hospital Three One hour lectures Three One hour lectures
2003-2005	Non-Respiratory Sleep Disorders Harvard Pulmonary Critical Care Fellows	Brigham and Women's Hospital, Massachusetts General Hospital One hour lecture
2009-	Advances in RLS Treatment, Medication Effects on Sleep, Psychiatric Sleep Medicine Sleep Medicine fellows	Beth Israel Deaconess Hospital, Three One hour lectures
2013-	Neurobiology of Sleep, Psychopharmacology of Sleep Disorders, Case studies in Psychiatric Sleep Medicine PGY2-PGY4 Psychiatry residents	Massachusetts General Hospital Nine one-hour lectures per year

Clinical Supervisory and Training Responsibilities

1992-1996	McLean Hospital sleep clinic and sleep laboratory, Psychiatry residents	4 hours per week
1997-2013	Brigham and Women's Hospital sleep clinic and sleep laboratory, Sleep fellows	2-4 fellows per year, 4-6 hours per week
2013-2016	Massachusetts General Hospital sleep clinic, Brigham and Women's Hospital Internal Medicine/Primary care residents/Research fellow(s)	1 resident per week, 20 weeks per year, 4-8 hours per week each
2018	Massachusetts General Hospital sleep clinic, Beth Israel Hospital sleep fellows	1 fellow per week, 40 weeks per year, 4 hours per week

Laboratory and Other Research Supervisory and Training Responsibilities

1996-present	Supervision of 1-3 research coordinators	4-8 hours per week total
2008-present	Supervision of 1 Psychiatry resident	2 hours per week
2004-present	Supervision of 1-2 post-doctoral research fellows and/or junior faculty	2 hours per week per fellow

Formally Supervised Trainees and Faculty

1997-1998	David Slamowitz, MD/private practice sleep medicine, Denver CO Career stage: fellow; Mentoring role: Clinical supervision; Accomplishments: independent clinical sleep laboratory and multicomponent practice
1998-2000	Robert Fogel, MD/private practice Career stage: fellow; Mentoring role: Clinical and academic supervision; Accomplishments: publication of 3 book chapters
2004-2006	Chang-Kook Yang, MD/ Department of Psychiatry, University of Busan, Korea Career stage: post-doctoral fellow; Mentoring role: Research supervision; Accomplishments: publication of 6 manuscripts/chapters
2006-2010	David Plante, MD/ Assistant Professor in Psychiatry, University of Wisconsin, Madison Career stage: resident and fellow; Mentoring role: Research supervision; Accomplishments: publication of 9 manuscripts/chapters and 1 edited book; Livingston Award from Department of Psychiatry, Massachusetts General Hospital; American Sleep Medicine Foundation fellowship, American Academy of Sleep Medicine
2011-2015	Wei-Chin Lin, MD / Taipei Veterans General Hospital, Taipei, Taiwan Career stage: post-doctoral fellow; Mentoring role: Research supervision; Accomplishments: publication of 1 manuscript and 2 in preparation
2011-2015	Sayaka Aritake-Okada, PhD/ Assistant Professor, Sports Psychiatry and Neuroscience Lab, Faculty of Sport Sciences, Waseda University, Japan Career stage: post-doctoral fellow, faculty; Mentoring role: Research supervision; Accomplishments: publication of 1 manuscript, multiple manuscripts in preparation
2011-present	Susan Mackie, MD/ Instructor in Medicine, Brigham and Women's Hospital Career stage: post-doctoral fellow, faculty; Mentoring role: Research supervision; Accomplishments: 2 published original investigations, 6 reviews, and one investigator-initiated grant
2015-present	Cathy McCall MD/ Resident in Psychiatry, Harvard-Longwood program Career stage: resident; Mentoring role: Research supervision; Accomplishments: 2 published review papers and one manuscript in preparation
2016-2017	Seung-Gul Kang MD/ Associate Professor, Department of Psychiatry, Gil Medical Center, Gachon University, School of Medicine, Incheon, Korea Career stage: faculty; Mentoring role: Research supervision; Accomplishments: 1 published paper and ongoing research projects
2016-2017	Tien-Yu Chen MD PhD/ Associate Professor, School of Medicine, National Defense Medical Center Taipei, Taiwan Career stage: faculty; Mentoring role: Research supervision; Accomplishments: 1 paper published

Formal Teaching of Peers (e.g., CME and other continuing education courses)

No presentations below were sponsored by outside entities

1994	Sleep and Insomnia in the Elderly	<i>Geriatric Psychiatry</i>	Massachusetts General Hospital, Harvard Medical School
1995	Restless Legs Syndrome in ESRD	<i>Renal Dialysis</i>	Brigham and Women's Hospital, Harvard Medical School
1995-1997	Review of Sleep Disorders	<i>Psychiatry</i>	McLean Hospital, Harvard Medical School
1996	Psychiatric Sleep Disorders, Narcolepsy, Parasomnias	<i>Diagnosis and Treatment of Sleep Disorders</i>	Brigham and Women's Hospital, Harvard Medical School
1996-1997, 2000-2006, 2013-2018	Psychopharmacology of Sleep Disorders	<i>Psychopharmacology</i>	Massachusetts General Hospital, Harvard Medical School
1996, 2002	Differential Diagnosis and Treatment of Insomnia, Depressive disorders	<i>Primary Medicine Today</i>	Pri-Med, Harvard Medical School, San Jose, CA
1997, 2003	Sleep Disorders	<i>Office Practice of Primary Medicine</i>	Pri-Med, Harvard Medical School
2000	Sleep Disorders	<i>Primary Care for Subspecialists</i>	Brigham and Women's Hospital, Harvard Medical School
2000, 2003	Sleep Medicine	<i>Intensive Review of Neurology</i>	Brigham and Women's Hospital, Harvard Medical School
2003	Major Depression, Excessive Daytime Sleepiness	<i>Pri-Med</i>	Harvard Medical School, Chicago, IL
2003-2010	Sleep Disorders	<i>Update in General Internal Medicine for Sub-specialists</i>	Brigham and Women's Hospital, Harvard Medical School
2004	Major Depression, Insomnia	<i>Pri-Med</i>	Harvard Medical School
2004-2008, 2010-2018	Sleep Disorders for Psychiatrists	<i>Psychiatry</i>	McLean Hospital, Harvard Medical School
2002-2006, 2009	Sleep Disorders	<i>Primary Care Internal Medicine, Principles and Practice</i>	Brigham and Women's Hospital, Harvard Medical School
2006-2010, 2017-2018	Sleep Disorders, Diagnosis and Management of	<i>Office Practice of Primary Care</i>	Brigham and Women's Hospital, Harvard Medical School

	Insomnia	Medicine	
2006, 2017-2018	Insomnia and Its Treatments	<i>Pri-Med</i>	Harvard Medical School
2007	Sleep Disorders and Anxiety	<i>Anxiety Disorders: Cognitive Behavioral Therapy and Pharmacotherapy Treatment Approaches</i>	Massachusetts General Hospital, Harvard Medical School
2010-2018	Treatment of Sleep Disorders	<i>Psychopharmacology: A Master Class</i>	Massachusetts Mental Health Center/Beth Israel Deaconess Medical Center, Harvard Medical School
2011	Assessment and Treatment of Insomnia in Depressed Patients	<i>Difficult to Treat Depression</i>	Massachusetts General Hospital Psychiatry Academy, Harvard Medical School
2011	Sleep disorders	<i>Lifestyle Medicine</i>	Harvard Medical School
2011	Persistent Insomnia in Treated Major Depression: Sleep Disorder or Mood Disorder?	<i>Difficult to Treat Depression</i>	Massachusetts General Hospital Psychiatry Academy
2014	Insomnia and Major Depression	<i>Depression, Anxiety and Stress in 2014</i>	McLean Hospital, Harvard Medical School
2014, 2016-2018	Periodic Limb Movements of Sleep and Restless Legs Syndrome	<i>Sleep! – A CME Course for Physicians</i>	Harvard Medical School
2015	Pharmacology of Sleep Disorder Management	<i>Issues in Psychiatric Diagnosis</i>	Massachusetts General Hospital Psychiatry Academy, Harvard Medical School
2016	Sleep and Psychiatric Disorders	<i>Frontiers of Psychiatric Treatment: Recent Advances and Future Directions</i>	Massachusetts General Hospital Psychiatry Academy, Harvard Medical School

Local Invited Presentations

No presentations below were sponsored by outside entities

1991	Sleep Disorders	Psychiatry Grand Rounds Beth Israel Deaconess Hospital, Boston, MA
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1992	Differential Diagnosis of Insomnia	Psychiatry Grand Rounds, Massachusetts General Hospital
1993	New Directions in Sleep Disorders	McLean Hospital Grand Rounds
1994	Review of Sleep Disorders	Psychiatry Grand Rounds Brockton Veterans Association Hospital, Brockton, MA
1995	Restless Legs Syndrome	Behavioral Neurology Grand Rounds, Brigham and Women's Hospital
1996	Sleep Disorders: Beyond Sleep Apnea	Pulmonary Grand Rounds, Massachusetts General Hospital
1996	Antidepressants and Sleep	Psychopharmacology Grand Rounds, McLean Hospital
1997	Sleep Related Eating Disorder	Psychiatry Grand Rounds, Brigham and Women's Hospital
1997	Sleep Disorders in Renal Failure	Renal Grand Rounds, Brigham and Women's Hospital
1997	Restless Legs Syndrome	Sleep Medicine Grand Rounds, Brigham and Women's Hospital
1997	Sleep in the Psychiatric Patient	Psychiatry Grand Rounds, Cambridge Hospital, Cambridge MA
1997	Sleep Disorders	McLean Hospital Grand Rounds
1997	Differential Diagnosis of Sleep Disorders in the Psychiatric Patient	Psychopharmacology Grand Rounds, McLean Hospital
1998	Sleep Disorders in Psychiatric Patients	Massachusetts Mental Health Center Grand Rounds, Boston, MA
1998	Sleep in the Psychiatric Patient	Department of Psychiatry Grand Rounds, Cambridge Hospital
1998	A Case of Restless Legs Syndrome and Sprue	Medicine Grand Rounds, Brigham and Women's Hospital
1999	Sleep Disorders	Rheumatology Grand Rounds, Brigham and Women's Hospital

2000	Sleep Related Eating Disorder	Endocrinology Grand Rounds, Brigham and Women's Hospital
2002	Sleep Disturbance in Diabetes	Joslin Diabetes Center Grand Rounds, Boston MA
2002	Insomnia Diagnosis and Treatment	Psychiatry Grand Rounds, Massachusetts General Hospital
2003	Excessive Daytime Sleepiness	McLean Hospital Grand Rounds
2003	Psychopharmacology of Sleep Disorders	Psychopharmacology Grand Rounds, Cambridge Hospital
2004	Differential Diagnosis and Treatment of Insomnia	Psychiatry Grand Rounds, Israel Deaconess Hospital
2005	Advances in Restless Legs Syndrome	McLean Hospital Grand Rounds
2006 2006	Psychopharmacology of Sleep Disorders Parasomnias	McLean Hospital Grand Rounds, Medicine Grand Rounds, Faulkner Hospital, Jamaica Plain, MA
2007	Differential Diagnosis and Treatment of Insomnia	Psychiatry Grand Rounds, Auburn Hospital, Cambridge
2007	Insomnia	Partners Physician Day, Boston, MA
2008	Sleep Disorders	Internal Medicine Grand Rounds, Mt. Auburn Hospital
2009	Epidemiology, Diagnosis, and Correlates of RLS	Sleep Medicine Grand Rounds, Brigham and Women's Hospital
2010	What We Can Learn about Depressive disorders from the Study of Insomnia	Psychiatry Grand Rounds, Massachusetts General Hospital
2011	RLS in Adults and Children	Sleep Medicine Grand Rounds, Children's Hospital
2011	Sleep Disorders in College Students	Mental Health Grand Rounds, Harvard University Health Service
2012	Sleep Medicine for Psychiatrists	Psychiatry Grand Rounds, Massachusetts General Hospital

2013	Sleep Medicine for Psychiatrists	Psychiatry Grand Rounds, St Elizabeth's Hospital, Brighton, MA
2013	Psychiatric Sleep Medicine	Psychiatry Grand Rounds, Mt. Auburn Hospital, Cambridge, MA
2013	Sleep Disorders in the Oncology Context	Mental Health Grand Rounds, Dana Farber Cancer Institute
2013	Sleep Disorders in Palliative Care	Palliative Care Grand Rounds, Massachusetts General Hospital
2015	Multimodal Imaging in Insomnia and Restless Legs Syndrome	McLean Hospital Imaging Center speaker series, McLean Hospital
2016	Sleep Disorders in the Psychiatric Context	Psychiatry Grand Rounds, Beth Israel Deaconess Hospital
2016	"Kicking the habit": Restless Legs Syndrome during Opioid Detoxification	McLean Hospital Alcohol and Drug Abuse Clinical Research Program speaker series, McLean Hospital
2016	Sleep Disorders	Internal Medicine Grand Rounds, Harvard University Health Service
2016	Restless Legs Syndrome: Progress and Pitfalls	Grand Rounds, Division of Sleep Medicine, Harvard Medical School
2018	Sleep Medicine: Progress, Pitfalls, and Promise	Psychiatry Grand Rounds, Massachusetts General Hospital
2018	Psychopharmacology of Sleep Disorders	Psychiatry Grand Rounds, St. Elizabeth's Hospital

Report of Regional, National and International Invited Teaching and Presentations

Invited Presentations and Courses

Regional

Those presentations below sponsored by outside entities are so noted and the sponsor is identified in parentheses

1992	Sleep Disorders	Psychiatry Grand Rounds, Lahey Clinic, Tufts University School of Medicine, Burlington MA
1992	The Treatment of Sleep Disorders	Massachusetts Psychiatric Society, Fall

		Scientific Program, Newton, MA
1993	Sleep Disorders	Psychiatry Grand Rounds, St. Elizabeth's Hospital, Tufts University School of Medicine
1994	Differential Diagnosis of Insomnia	Psychiatry Grand Rounds, Boston Veterans Administration Hospital, Boston University School of Medicine & Harvard Medical School, Boston, MA
1994	Sleep Disorders in Psychiatric Perspective	Boston University School of Medicine, University Hospital Grand Rounds, Boston MA
1995	Sleep Related Eating Disorder	Massachusetts Institute of Technology Health Service, Grand Rounds, Cambridge MA
1998	Sleep Disorders,	Solomon Carter Fuller Hospital Grand Rounds, Boston University School of Medicine, Boston, MA
1999	Differential Diagnosis and Treatment of Insomnia	Medicine Grand Rounds, Central Maine Medical Center, Portland, ME (Eli Lilly)
1999	Psychopharmacology of Sleep Disorders	Bedford Veterans Association Hospital Grand Rounds, Boston University School of Medicine, Bedford, MA (Eli Lilly)
2000	Sleep Disorders	Carney Hospital Medical Grand Rounds, Tufts University School of Medicine, Dorchester, MA
2001	Sleep Related Eating Disorder	Nutrition Grand Rounds, New England Medical Center, Tufts University School of Medicine, Boston, MA
2002	Evaluation and Management of Excessive Daytime Sleepiness in the Psychiatric Patient	Internal Medicine Grand Rounds, Shattuck Hospital, Boston, MA
2002	Sleep Disorders	Baystate Medical Center Grand Rounds, Springfield, MA
2002	Insomnia in the Psychiatric Patient	Massachusetts Psychiatric Society, Annual Psychopharmacology Conference
2002	Restless Legs Syndrome	Medicine Grand Rounds, Faulkner Hospital, Tufts University School of Medicine,

		Jamaica Plain, MA
2003	Sleep Disorders and the Psychiatric Patient	Psychiatry Grand Rounds, Boston University School of Medicine, Boston Medical Center, Boston, MA
2003	Mood Disorders and Sleep	Psychiatry Grand Rounds, St. Elizabeth's Hospital, Boston, MA
2004	Sleep Disorders	Psychiatry Grand Rounds, Shattuck Hospital, Boston, MA
2005	Restless Legs Syndrome for the Psychiatrist	Psychiatry Grand Rounds, St. Elizabeth's Hospital, Boston, MA (Boehringer-Ingelheim)
2005	Sleep Disorders	Annual Peter Mencher Memorial Grand Rounds, Department of Medicine, Winchester Hospital, Winchester, MA
2006	Sleep Disorders	Internal Medicine Grand Rounds, Lahey Clinic, Burlington, MA
2007	Sleep and its Relationship to Psychiatric Disorders	Keynote speaker, American Psychiatric Nursing Association annual meeting, Cambridge, MA
2008	Advances in Restless Legs Syndrome	Psychiatry Grand Rounds, Tufts Medical Center, Boston, MA
2008	Restless Legs Syndrome	Medicine Grand Rounds, New England Baptist Hospital, Boston, MA
2010	What the Psychiatrist Needs to Know about Sleep Disorders	Psychiatry Grand Rounds, North Shore Medical Center, Salem MA
2010	Sleepless in the Merrimack Valley: Update on Insomnia	Medicine Grand Rounds, Lowell General Hospital, Lowell, MA
2011	Restless Legs Syndrome: Neurobiology, Cardiovascular Correlates and Treatments	Neurology Grand Rounds, Boston University School of Medicine, Boston, MA
2012	Sleep-Related Movement Disorders; Diagnosis and Treatment of Insomnia	Mini-residency in Dental Sleep Medicine, Tufts University Boston, MA
2012	Recent findings in the Neurobiology of Insomnia: Relevance for Major Depressive Disorder	Psychiatry Grand Rounds Dartmouth Medical School and Dartmouth- Hitchcock Medical Center, Hanover NH
2013	RLS and PLMS: New Discoveries	Massachusetts Sleep Society, Newton, MA

2015	Restless Legs Syndrome: The Good, the Bad and the Ugly	Sleep Grand Rounds, Section of Pulmonary, Critical Care and Sleep Medicine, Yale University School of Medicine, New Haven, CT
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National

Those presentations below sponsored by outside entities are so noted and the sponsor is identified in parentheses

1996	Treatment of Sleep Disorders in Psychiatric Patients	Psychiatry Grand Rounds, Lennox Hill Hospital, New York University Medical School, New York, New York
1998	Treatment of Restless Legs Syndrome in End Stage Renal Disease	Associated Professional Sleep Societies, New Orleans, LA
1999	Psychopharmacology of Sleep Disorders	Psychiatry Grand Rounds, Lutheran General Hospital, Chicago, IL (Eli Lilly)
1999	Sleep Disorders and Dysomnias	American Psychiatric Association Annual Meeting, Washington, DC
2000	Sleep Disorders and Dysomnias	American Psychiatric Association Annual Meeting Chicago, IL
2001	Restless Legs Syndrome	Neurology Grand Rounds, Emory University Medical School, Atlanta GA
2001	Restless Legs Syndrome	Grand Rounds, Allegheny General Hospital, Drexel University College of Medicine, Pittsburgh, PA
2001	Disorders of Excessive Daytime Somnolence: Diagnosis and Management	Session chair, American Psychiatric Association Annual Meeting, New Orleans, LA (Cephalon)
2001	Sleep Disorders and Dysomnias	American Psychiatric Association Annual Meeting, New Orleans, LA
2002	Managing the Disordered Sleep of Anxiety Disorders	Psychopharmacology Update, Medical College of Ohio, Toledo, OH
2002	Disorders of Excessive Daytime Somnolence: Diagnosis and Management,	Annual Psychopharmacology Update, Nevada Psychiatric Association, Las Vegas, NV
2002	Periodic Leg Movements of Sleep	Meet the Professor, Associated Professional

		Sleep Societies Annual Meeting, Chicago, IL
2002	Managing the Disordered Sleep Associated with Anxiety Disorders	American Psychiatric Association Annual Meeting, Philadelphia, PA (Pfizer)
2002	Sleep Disorders and Dysomnias	American Psychiatric Association Annual Meeting, Philadelphia, PA
2002	Identification and Management of Daytime Fatigue and Sleepiness in Psychiatry	Session chair, American Psychiatric Association symposium, Philadelphia, PA (Cephalon)
2003	Sleep Disorders and Dysomnias	American Psychiatric Association Annual Meeting San Francisco, CA
2003	Treatment of Insomnia in the Psychiatric Patient	American Psychiatric Association Annual Meeting, San Francisco, CA
2003	Midwest Update in Sleep Disorders	St. Louis University School of Medicine, St. Louis, MO
2003	Bipolar Disorder and Sleep	Psychiatry Grand Rounds, Philadelphia Veterans Association, Philadelphia, PA
2003	Overview and Update on Sleep Disorders in Medicine, Dysomnias	American Psychiatric Association Annual Meeting, San Francisco, CA
2003	Depression, Apathy, and Fatigue in Neuropsychiatric Disorders	Session chair, American Psychiatric Association Annual meeting, San Francisco, CA
2003	Update in Restless Legs Syndrome and Periodic Limb Movement Disorder	Associated Professional Sleep Societies Annual Meeting, Chicago, IL
2003	End Stage Renal Disease Related Restless Legs Syndrome	Associated Professional Sleep Societies Annual Meeting, Chicago, IL
2003	Management of Insomnia and Sleep Disorders in Restless Legs Syndrome Patients	Associated Professional Sleep Societies Annual Meeting, Chicago, IL
2004	New Pharmacologic Approaches for the Treatment of Insomnia	American Psychiatric Association Annual Meeting Atlanta, GA
2004	Evaluation and treatment of parasomnias (session chair)	American Psychiatric Association Annual meeting, Philadelphia, PA
2004	Current and Future Treatments of Insomnia	American Psychiatric Association Annual Meeting, New York, NY (Neurocrine/Pfizer)
2004	Sleep Disorders and Dysomnias	American Psychiatric Association Annual

		Meeting , New York, NY
2004	Exploring the true morbidity of insomnia	Session chair, American Psychiatric Association Annual Meeting, New York, NY (Neurocrine/Pfizer)
2004	Methodological Issues in Insomnia: Treatment Trials and Implications for the Development of Future Therapies	Associated Professional Sleep Societies Annual Meeting, Philadelphia, PA
2004	Update on Evaluation of Treatment Efficacy in the Management of Chronic Insomnia	New Clinic Drug Evaluation Unit Annual Meeting, Phoenix, AZ
2005	The many faces of RLS: RLS in Unique Medical Conditions	Associated Professional Sleep Societies Annual Meeting , Denver, CO
2005	Evaluation and treatment of parasomnias (session chair)	Associated Professional Sleep Societies Annual Meeting, Denver, CO
2005	Best Practices in Restless Legs Syndrome (RLS) and Periodic Limb Movement Disorder (PLMD)	Associated Professional Sleep Societies Annual Meeting, Denver, CO
2005	Arousing from Sleep to Eat: Night Eating Syndrome, Sleep Related Eating Disorder, and Central vs. Peripheral Circadian Clocks	Session chair, Associated Professional Sleep Societies Annual Meeting, Denver, CO
2005	New Pharmacologic Approaches to the Treatment of Insomnia	American Psychiatric Association Annual Meeting, Atlanta, GA
2005	Novel Strategies to Treat Insomnia	American Psychiatric Association Annual Meeting, Atlanta, GA
2005	Sleep Disorders and Dysomnias	American Psychiatric Association Annual Meeting, Atlanta, GA
2006	The Relevance of Sleep for Anxiety Disorders	Anxiety Disorders Association of America, Miami, FL (Sepracor)
2006	Management of Augmentation	Associated Professional Sleep Studies Annual Meeting, Salt Lake City, UT
2006	Management of Patient Presenting With RLS and Depression	Associated Professional Sleep Societies Annual Meeting, Salt Lake City, UT
2006	Movement Disorders in Patients with OSAS (session chair)	World Congress of Sleep Apnea, Toronto, Canada
2006	RLS in Unique Medical Conditions: Management of Secondary RLS	Associated Professional Sleep Societies Annual Meeting, Salt Lake City, UT

2006	What the Psychiatrist Needs to Know About Sleep-Related Movement Disorders	Session chair, American Psychiatric Association Annual Meeting, Toronto, Canada
2007	Clinical Pathways: An Interactive Case Based Approach to the Management of RLS	American Psychiatric Association Annual Meeting, San Diego, CA (Boehringer Ingelheim)
2007	Recognition and Management of Restless Legs Syndrome (RLS) in Psychiatric Practice (session chair)	American Psychiatric Association Annual Meeting, San Diego, CA (Boehringer Ingelheim)
2007	RLS and Psychiatric Disorders	Associated Professional Sleep Societies Annual Meeting, Minneapolis, MN
2007	Treatment of Restless Legs Syndrome	American Academy of Sleep Medicine Board Review Course, Denver, CO
2008	Restless Legs Syndrome	Sleep Grand Rounds Case Western Reserve Medical School, University Hospital, Cleveland, OH
2009	Mortality and Morbidity in Renal Failure patients affected with Restless Legs Syndrome/Periodic Leg Movements of Sleep	Associated Professional Sleep Societies Annual Meeting, Seattle, WA (UCB Pharma)
2009	Management Challenges in RLS	Meet the Professor, Associated Professional Sleep Societies Annual Meeting, Seattle, WA
2009	Neurobiological Correlates of Insomnia (session chair)	Associated Professional Sleep Societies Annual Meeting, Seattle, WA
2010	Restless Legs Syndrome in Menopause	North American Menopause Society Annual Meeting, Chicago, Ill
2010	RLS: Correlates and Comorbidities	Symposium chair, Associated Professional Societies Annual Meeting, Minneapolis, MN (UCB Pharma)
2010	New Directions in Understanding the Pathophysiology, Comorbidities, and Treatment of Restless Legs Syndrome	Session chair, Associated Professional Sleep Societies Annual Meeting, San Antonio, TX (UCB Pharma)
2011	Treatment of Restless Legs Syndrome (RLS)	Best Practices course, Associated Professional Sleep Societies Annual Meeting, Minneapolis, MN

2011	Neurochemical Changes in Brain in Sleep Disorders: Results from 31P and 1H Magnetic Resonance Spectroscopy	Session chair, Associated Professional Sleep Societies Annual Meeting, Minneapolis, MN
2011	Diagnosis and Long-Term Management of Patients with Complex Restless Legs Syndrome	Session chair, Associated Professional Sleep Societies Annual Meeting, Minneapolis, MN (UCB Pharma)
2011	Does RLS Cause Anxiety/Mood Disorders and Cardiovascular Disease?	Associated Professional Sleep Societies Annual Meeting, Minneapolis, MN
2012	Restless Legs Syndrome	Year in Review course, Associated Professional Sleep Societies Annual Meeting, Boston, MA
2012	Recent Findings in the Neurobiology of Insomnia: Marker of Resilience to Major Depressive Disorder?	Psychiatry Grand Rounds Stanford University Medical Center, Stanford, CA
2012	Comorbid RLS and Psychiatric Illness: Clinical Conundrums	Associated Professional Sleep Societies Annual Meeting, Boston, MA (UCB Pharma)
2012	Should Dopamine Agonists Still be First-line Treatment for Restless Legs Syndrome?	Session chair, Associated Professional Sleep Societies Annual Meeting, Boston, MA
2012	Sleep-related Eating Disorder: Features, Diagnosis, Treatment and Many Remaining Questions	Meet the Professor, Associated Professional Sleep Societies Annual Meeting, Boston, MA
2013	Treatment of Sleep-Related Movement Disorders	State of the Art for Clinical Practitioners, Associated Professional Sleep Societies Annual Meeting, Baltimore, MD
2014	RLS Patient Characteristics: Correlates and Consequences	Southern Sleep Society, Memphis, TN
2014	RLS Treatment Guidelines	Southern Sleep Society, Memphis, TN (UCB Pharma)
2014	RLS: Recent Advances and Future Directions	Sleep Medicine Grand Rounds, University of Pennsylvania School of Medicine, Philadelphia, PA
2014	RLS Treatment Guidelines and Recommendations	Associated Professional Sleep Societies Annual Meeting, Boston, MA (UCB Pharma)
2015	RLS/PLM Complicated by Psychiatric Conditions or Renal Failure	Associated Professional Sleep Societies Annual Meeting, Seattle, WA

2016	Neurostimulation for RLS	Session co-chair, Associated Professional Sleep Societies Annual Meeting, Denver, CO
2016	Restless Legs Syndrome: Progress and Pitfalls	Visiting Professor and Neurology Grand Rounds, Cleveland Clinic, Cleveland, OH
2017	Restless Legs Syndrome	State of the Art for Clinical Practitioners Associated Professional Sleep Societies Annual Meeting, Boston, MA
2017	Oral Iron in Adults: Efficacy and Limitations	Associated Professional Sleep Societies Annual Meeting, Boston, MA
2018	RLS, PLMS, cardiovascular disease and mortality: a review of epidemiologic associations and potential mechanisms	Meet the Professor, Associated Professional Sleep Societies Annual Meeting, Baltimore, MA
2018	Sedative hypnotic initiation and maintenance	Associated Professional Sleep Societies Annual Meeting, Baltimore, MA

International

Those presentations below sponsored by outside entities are so noted and the sponsor is identified in parentheses

1998	Sleep Disorders and Dysomnias	American Psychiatric Association Annual Meeting Toronto, Canada
2004	Long Term Experience with Dopaminergic Agents	Third International Scientific Symposium on Parkinson's Disease and Restless Legs Syndrome, Cannes, France (Boehringer-Ingelheim)
2004	Considering the Causes of RLS	European Federation of Neurological Societies Annual Meeting, Cannes, France (GlaxoSmithKline)
2005	RLS and its impact on sleep	World Association of Sleep Medicine, Berlin, Germany
2006	Depression and RLS	Fourth International Scientific Symposium on Parkinson's Disease and Restless Legs Syndrome, Stresa, Italy (Boehringer-Ingelheim)
2006	Mood Issues and RLS 2006 – An Update	Fifth International Scientific Symposium on Parkinson's Disease and Restless Legs Syndrome, Barcelona, Spain (Boehringer-Ingelheim)
2006	Restless Legs Syndrome and Psychiatric Disorders – Demonstrating a Relationship	American Psychiatric Association Annual Meeting, Toronto, Canada
2006	The Restless Legs Syndrome: diagnosis and	World Congress of Sleep Apnea, Montreal,

	treatment	Canada (Boehringer-Ingelheim)
2007	RLS in ESRD	World Association of Sleep Medicine, Bangkok, Thailand
2008	State of the Art in Managing RLS	Sixth International Scientific Symposium on Parkinson's Disease and Restless Legs Syndrome, Paris, France (Boehringer-Ingelheim)
2012	Augmentation and Restless Legs Syndrome	Visiting Professor, Department of Neurology, Innsbruck Medical University, Innsbruck, Austria
2013	The Effect of Rotigotine on Nocturnal Blood Pressure Changes and PLMS in Patients with Idiopathic RLS: the ENCORE Study	World Association of Sleep Medicine, Valencia, Spain
2013	Magnetic Resonance Spectroscopy in Primary Insomnia	Freiburg Institute for Advanced Studies, University of Freiburg, Freiburg, Germany
2014	Bidirectional Relationships of RLS and Cardiovascular disease	European RLS Study Group, Munich, Germany
2015	Respiratory-related Leg Movements	IRLSSG/EURLSSG Taskforce for the Scoring Criteria of PLMS, Troina, Sicily
2015	Epidemiological Associations of RLS and Cardiovascular disease (session chair)	IRLSSG/EURLSSG RLS/WED Science Summit, Monterey, CA
2016	Restless Legs Syndrome: Progress and Pitfalls	Japanese Sleep Research Society, Tokyo, Japan (Otsuka)
2016	RLS and Cardiovascular Disease: A Review of Epidemiologic Associations and Potential Mechanisms	Japanese Sleep Research Society, Tokyo, Japan
2017	Iron Supplementation in RLS: When and How? PLMD and PLM: necessity to treat? (Invited presentations)	Swiss Sleep Society, Lugano, Switzerland
2017	Main Advantages and Problems in Dopaminergic Treatment	World Sleep Society, Prague, Czech Republic
2017	New IRLSSG Standards of Practice for Iron Treatment	World Sleep Society, Prague, Czech Republic

Report of Clinical Activities and Innovations

Current Licensure and Certification

1988	Massachusetts Medical License
1988	California Medical License
1991	American Board of Psychiatry and Neurology (Psychiatry)
1993	American Board of Sleep Medicine
2013	American Board of Psychiatry and Neurology (Sleep Medicine)

Practice Activities

1991-1996	Ambulatory Care	Sleep Medicine, McLean Hospital	16 hours per week
1996-2013	Ambulatory Care	Sleep Medicine, Brigham and Women's Hospital	8 hours per week
2013-present	Ambulatory Care	Sleep Medicine, Massachusetts General Hospital	12 hours per week

Clinical Innovations

Development of McLean Hospital Sleep Disorders Center (1991-1996)	Reorganized the Sleep Disorder Center administratively, clinically, and scientifically, orienting it to outpatients, cost efficiency, and a teaching and research site.
Described the phenotype and developed innovative treatments for Sleep-related Eating Disorder (2003-)	First author papers published in <i>J. Clinical Psychiatry</i> and <i>Sleep Medicine</i> describing the first use of topiramate for this disorder, which is now considered the first-line treatment choice.
Leadership role in the development of pharmacologic treatments for Restless Legs Syndrome (2006-)	Papers published in <i>Neurology</i> and <i>Movement Disorders</i> reporting the results of pivotal trials leading to FDA approval of pramipexole, gabapentin enacarbil and rotigotine for the treatment of restless legs syndrome. Authored guidelines on RLS treatment for national and international organizations.
Medical director for sleep laboratory at Brigham and Women's Hospital (1996-2012)	Helped develop an integrated care model of Sleep Medicine with multidisciplinary outpatient care, inpatient sleep studies, and provision of medical equipment at one site.
Development of Psychiatric Sleep Medicine clinical and research service at Massachusetts General Hospital (2013-)	Founded the Sleep Disorders Clinical Research Program, a subspecialty clinical service which integrates the education of Psychiatry, Neurology and Internal Medicine residents and sleep research fellows into clinical research in the overlap of sleep disorders and psychiatric illness.

Report of Education of Patients and Service to the Community

No educational materials below were sponsored by outside entities

Activities

2002	Restless Legs Syndrome Foundation, first national meeting, St Louis, MO	Overview of restless legs syndrome, lecture
2005	Newton Public Library, Newton MA	Sleep and its disorders, lecture
2009	Restless Legs Syndrome Foundation Scientific Conference, Baltimore, MD	Update on RLS diagnosis and treatment, lecture
2011-present	Premedical advisor (1-4 undergraduates per year)	Harvard University
2013	Temple Isiah, Lexington, MA	Sleep Disorders, lecture
2015	Restless Legs Syndrome Foundation, webinar	Augmentation suffering and what can be about it, lecture
2016	Restless Legs Syndrome Foundation, webinar	RLS and depression
2017	Restless Legs Syndrome Foundation webinar	Neurostimulation for restless legs syndrome
2017	Massachusetts General Hospital EAP program	Getting your best sleep

Podcasts:

Practice guideline summary: Treatment of restless legs syndrome in adults Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology, 2016, <https://www.aan.com/rss/search/home/episodedetail/?item=3207>.

Books, monographs, articles and selected presentations in other media

1996	Sleep eating	Dateline NBC	
1998	Sleep-related eating disorder	Oprah Winfrey Show	
1999	Restless Legs Syndrome	Good Morning America	
2001	Improving Sleep: A Guide to Getting a Good Night's Rest	Harvard Medical School Publications	Patient education pamphlet
2003	10 Tips for a Good Night's Sleep	MassHealth Druglist	https://masshealthdruglist.ehs.state.ma.us/MHDL/pubdownloadpdfcurrent.do?id=39
2003	Seeking calm for restless legs	LA Times	http://articles.latimes.com/2003/sep/15/health/he-legs15
2003	The man who mistook his wife for a deer	NY Times Magazine	http://www.nytimes.com/2003/02/02/magazine/the-man-who-mistook-his-wife-for-a-deer.html?pagewanted=all

2003	When the brain disrupts the night	NY Times	http://www.nytimes.com/2003/01/07/science/when-the-brain-disrupts-the-night.html?pagewanted=all
2004	Sleepeaters don't wake up for their nighttime binges	Washington Post	https://www.washingtonpost.com/archive/lifestyle/wellness/2004/09/07/hungry-in-the-dark/5c0dad34-4082-4d73-b35a-7e262b880609/
2005	New class of insomnia drugs to hit market	NBC News	http://www.nbcnews.com/id/8632174/ns/health-health_care/t/new-class-insomnia-drugs-hit-market/#.Vx5oBdQrLct
2006	Study Links Ambien Use to Unconscious Food Forays	NY Times	http://www.nytimes.com/2006/03/14/health/14sleep.html?_r
2007	Inside the Strange World of Sleep Eaters	Discover Magazine	http://discovermagazine.com/2007/medical-mysteries/strange-world-of-sleep-eaters
2007	Restless Legs Syndrome	The Today Show	
2007	Restless Legs Syndrome Linked to Obesity, Fat Waistlines	ABC News	http://abcnews.go.com/Health/MindMoodNews/story?id=7272011&page=1
2007	Restless Legs Syndrome: New Gene Clues	WebMD	http://www.webmd.com/sleep-disorders/news/20070718/restless-legs-syndrome-new-gene-clues
2007	Scientists Discover Sleep-Kicking Gene	ABC News	http://abcnews.go.com/Health/Sleep/scientists-discover-sleep-kicking-gene/story?id=3390545
2008	I've had insomnia for years. Is there a biological cause?	Boston Globe	http://archive.boston.com/news/health/articles/2008/11/03/ive_had_insomnia_for_years_is_there_a_biological_cause/
2008	Restless legs linked with heart problems	Reuters	http://www.reuters.com/article/us-heart-rls-idUSN3159019220071231
2009	Cost-Effective Ways to Fight Insomnia	NY Times	http://www.nytimes.com/2009/06/06/health/06patient.html
2010	Binge Eating During Sleep	NY Times	http://well.blogs.nytimes.com/2010/04/07/binge-eating-during-sleep/
2010	Motion sickness: Restless legs syndrome keeps you going (even if you want to stop)	Boston Globe	http://archive.boston.com/yourtown/cambridge/articles/2010/05/17/restless_legs_syndrome_keeps_you_going_even_if_you_want_to_stop/
2010	Raiding the Refrigerator, but Still Asleep	NY Times	http://www.nytimes.com/2010/04/07/health/07eating.html
2010	The Secrets of Sleep	National Geographic	http://ngm.nationalgeographic.com/2010/05/sleep/max-text
2010	What's <i>really</i> keeping you awake	Self	http://www.self.com/wellness/health/2010/01/insomnia-and-other-health-concerns/
2012	Sleep Experts Awaken Interest in Parasomnias	Psychiatric News	http://psychnews.psychiatryonline.org/doi/10.1176/pn.47.19.psychnews_47_19_18-a

2013	Healthful Habits Can Help Induce Sleep Without The Pills	NPR	http://www.npr.org/sections/health-shots/2013/12/16/250256086/healthy-habits-can-help-induce-sleep-without-the-pills
2013	On treating sleep disorders	Psych Central	http://pro.psychcentral.com/this-months-expert-john-w-winkelman-m-d-ph-d-on-treating-sleep-disorders/002099.html
2014	8 Things Your Sleep Habits Say About You	Prevention	http://www.prevention.com/health/health-concerns/what-insomnia-sleep-walking-and-fatigue-mean
2014	Sleeping in your 70s	Boston Globe	https://www.bostonglobe.com/business/2014/11/16/sleeping-your/eNjzR2Bi65TaXxjmxbhrgL/story.html
2014	Study ties troubled sleep to lower brain volume	Good Morning America	http://www.gmanetwork.com/news/story/351803/lifestyle/healthandwellness/study-ties-troubled-sleep-to-lower-brain-volume
2014	Study ties troubled sleep to lower brain volume	Reuters	http://www.reuters.com/article/us-sleep-idUSBREA261JC20140307
2015	Ask well: Do sleeping pills induce restorative sleep?	NY Times	http://well.blogs.nytimes.com/2015/12/11/ask-well-do-sleeping-pills-induce-restorative-sleep/?_r=0
2016	A New Study Proves It: You Should Totally Sleep In This Weekend	Glamour	http://www.glamour.com/story/why-you-should-sleep-in-this-w
2016	AAN Releases First Treatment Guideline on Restless Legs Syndrome	Medscape	http://www.medscape.com/viewarticle/872681
2017	Are leg and foot cramps waking you up at night?	Washington Post	https://www.washingtonpost.com/national/health-science/are-leg-and-foot-cramps-waking-you-up-at-night-youre-not-alone/2017/08/04/14490744-761b-11e7-8f39-eeb7d3a2d304_story.html?utm_term=.a47fb423000f

Report of Scholarship

Peer-reviewed publications

Research Investigations:

1. Solomon PR, Crider A, **Winkelman JW**. Disrupted latent inhibition in the rat with chronic amphetamine or haloperidol-induced supersensitivity: Relationship to schizophrenic attention disorder. *Biol Psychiatry* 1981;16:519-537.
2. McCarley RW, **Winkelman JW**, Duffy FH. Human cerebral potentials associated with REM sleep rapid eye movements: Links to PGO waves and waking potentials. *Brain Res* 1983;274:359- 364.
3. **Winkelman JW**, Chertow G, Lazarus JM. Restless legs syndrome in end-stage renal disease. *Am J Kidney Dis* 1996;28:372-378.
4. Cunningham SL, **Winkelman JW**, Dorsey CM, Lukas SE, Richardson GS, Sholar MB. An electromyographic marker for neuroleptic-induced akathisia: preliminary measures of sensitivity and specificity. *Clinical Neuropsychopharmacology* 1996;19:321-332.
5. Dorsey CM, Lukas SE, Teicher MH, Harper D, Cunningham SL, Taylor JF, **Winkelman JW**, Satlin A. Effects of passive body heating on sleep of older female insomniacs. *J Ger Psychiatry Neurol* 1996;9:83-90.
6. **Winkelman JW**, Goldman H, Piscatelli N, Lukas S, Dorsey CM, Cunningham S. Are thyroid function tests necessary in patients with suspected sleep apnea? *Sleep* 1996;19:790-793.
7. Pradhan P, Gliklich R, **Winkelman JW**. Rates of obstructive sleep apnea in patients referred for evaluation of snoring. *Laryngoscope* 1996;106:1393-1397.
8. **Winkelman JW**. Clinical and polysomnographic features of sleep-related eating disorder. *J Clin Psychiatry* 1998;59:14-19.
9. **Winkelman JW**. The evoked heart rate response to periodic leg movements of sleep. *Sleep* 1999;22:575-580.
10. **Winkelman JW**, Herzog DB, Fava, M. The prevalence of sleep-related eating disorder in psychiatric and non-psychiatric populations. *Psychol Med* 1999;29:1461-1466.
11. Gliklich RE, Taghizadeh F, **Winkelman JW**. Health status in patients with disturbed sleep and obstructive sleep apnea. *Otolaryngol Head Neck Surg* 2000;122:542-546.
12. **Winkelman JW**. Schizophrenia, obesity and obstructive sleep apnea. *J Clin Psychiatry* 2001;61:8-11.
13. **Winkelman JW**. Treatment of nocturnal eating syndrome and sleep-related eating with topiramate. *Sleep Med* 2003; 4:243-246.

14. **Winkelman JW**, Johnston L. Augmentation and tolerance with long-term pramipexole treatment of restless legs syndrome (RLS). *Sleep Med* 2004;5:9-14.
15. **Winkelman JW**, James L. Serotonergic antidepressants are associated with REM sleep without atonia. *Sleep* 2004;27:317-321.
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Abstracts, Poster Presentations and Exhibits Presented at Professional Meetings (unpublished, in last year):

1. **Winkelman JW**, Mei LA, Platt S, Schoerning L. Pilot open-label trial of transcutaneous electrical nerve stimulation (TENS) below the knee for the treatment of restless legs syndrome (RLS). Poster presentation at Associated Professional Sleep Societies, Denver, CO, 2016.
2. Winkelman JW, Mei L, Schoerning L, Gonenc A. Disrupted white matter integrity in insomnia and major depressive disorder: correlations with subjective and objective sleep parameters. Oral presentation at World Sleep Society, Prague, CZ, 2017
3. McCall C**, Bianchi M, Winkelman JW. Respiratory-related leg movements are associated with serotonergic antidepressants but not bupropion. Poster presentation at World Sleep Society, Prague, CZ, 2017.
4. Bottary RM, Mei L, Schoerning L, Jensen JE, Winkelman JW. Depression severity, but not objective or subjective sleep disturbance, mediates glutamate reductions in the ACC in major depressive disorder. Poster presentation at World Sleep Society, Prague, CZ, 2017.

** mentee

Narrative Report

Introduction

My clinical, teaching, and research activities are at the intersection of psychiatry and sleep medicine, focusing on insomnia and restless legs syndrome (RLS). After completing my residency training in Psychiatry and a fellowship in Sleep Medicine at the Massachusetts General Hospital (MGH), I joined the faculty of Harvard Medical School (HMS), leading sleep laboratories and clinics at McLean Hospital, then at Brigham and Women's Hospital and currently at MGH, where I am the chief of the Sleep Disorders Clinical Research Program. For twenty years I have led efforts in clinical physiology, drug development, treatment guidelines, and disease classification in sleep medicine. I have mentored residents and fellows from multiple disciplines, and lectured to post-graduates regionally, nationally and internationally. My research in insomnia and RLS has been published in high impact journals and is currently supported by an RO1 grant and by investigator-initiated grants.

Clinical Expertise and Innovation

I receive referrals for consultations from both generalist and specialist colleagues regionally and nationally, particularly for complex patients with RLS, insomnia, parasomnias, and with co-morbid psychiatric illness and sleep disorders. I delivered the "State of the Art" or "Best Practices" lectures on RLS at 3 recent annual sleep meetings, chaired the American Academy of Neurology RLS Treatment Guidelines committee (just published in *Neurology*), have been a writing member of the committees establishing both RLS diagnostic criteria and treatment guidelines for multiple national and international organizations, and am senior author of the UpToDate section on Nocturnal Leg Cramps. My work as national coordinating PI and first author on Phase III pivotal trials contributed to FDA-approval of pramipexole (*Neurology*) and gabapentin enacarbil (*Movement Disorders*) for RLS. I was the senior author on a long-term clinical trial on RLS in the *New England Journal of Medicine*, comparing efficacy and augmentation with pramipexole and pregabalin. As chair of the American Academy of Sleep Medicine (AASM) Nosology Committee (2004-2007) I initiated efforts to revise the sleep disorders classification system, subsequently published as the *International Classification of Sleep Disorders-Third Edition*. My papers on the phenotype and prevalence of sleep-related eating disorder (SRED) were some of the first on this disorder, and my descriptions of SRED treatment with topiramate have led to that medication's use as first-line treatment. I recently authored the Clinical Practice review on Insomnia Disorder in the *New England Journal of Medicine* which received over 43,000 HTML and PDF page views in the first year after its publication, which is in the top 90% of all NEJM papers. I am the author of the upcoming Overview of Insomnia Treatments for UpToDate. Based in large part on my clinical and research experience, I was senior editor of the textbook *Foundations of Psychiatric Sleep Medicine*, written by an international group of leaders in the field. It was recently advertised by Cambridge University Press as one of their "best sellers." I also co-edited the *Encyclopedia of Sleep Science*, and the two AASM publications *Case Book of Sleep Medicine for ICSD2* and more recently *Case Book of Sleep Medicine for ICSD3*.

Teaching

I have been actively involved in teaching and supervision of medical students and residents since I joined the HMS faculty. I published a curriculum for the teaching of sleep disorders to psychiatry residents in the *Harvard Review of Psychiatry*, and lecture on sleep disorders in multiple Harvard-affiliated psychiatry residency and sleep fellowship programs. I chaired the Harvard CME course on Sleep Medicine beginning in 1998, teach in multiple MGH-BWH-McLean-sponsored CME courses and give Grand Rounds presentations across the nation. I have chaired multiple sleep-related symposia at the American Psychiatric Association annual meetings and have chaired symposia and/or post-graduate courses at the Associated Professional Sleep Societies annual meetings nearly every year since 2004.

Supporting Activity: Investigation

My clinical research focuses on insomnia and the sleep-related movement disorders (particularly RLS). Our finding of a reduction in cortical GABA levels using magnetic resonance spectroscopy (MRS) was the first demonstration of any neurochemical abnormality in insomnia and was a rapid publication in *Sleep*. We subsequently replicated this finding with anatomical specificity to the anterior cingulate and occipital cortices, published in *Neuropsychopharmacology*. This work investigating CNS GABA and glutamate levels using MRS and structural imaging has been extended to both insomnia and major depression and is now supported by a 5-year RO1 from the NIMH. My other clinical research focus is on the relationship of sleep disorders to medical illness. We published seminal studies on: the autonomic consequences of periodic leg movements of sleep (PLMS) in *Sleep*; the elevated risk of cardiovascular disease in RLS (in *Neurology*, in *Sleep*, and in *Circulation*); the increased risk of mortality in insomnia (*Circulation*); and on the elevated mortality risk that RLS confers in patients without medical illness (*Neurology*) and in those with end stage renal disease (ESRD) (*American Journal of Kidney Disease*).

Supporting Activity: Administration and Institutional Service

I have been responsible for clinical management of clinical sleep programs and/or sleep laboratories at McLean Hospital (1991-1996), Brigham and Women's Hospital (1996-2013) and MGH (2013-present) for 20 years. I have organized CME courses on Sleep Medicine at the local, national and international level for nearly 20 years.

Summary

The focus of my clinical and investigative efforts is in the areas of RLS, insomnia, and the intersection of sleep disorders and psychiatry. I see several hundred new patients, and follow many more, with these disorders per year. My leadership positions in national and international organizations has helped to promote awareness of RLS and has assisted with the dissemination of both standardized diagnostic criteria and efficacious and FDA-approved therapeutics over the past 20 years. My epidemiology and clinical physiology research in RLS initiated an active area of international investigation on the cardiovascular consequences of that disorder, in which I continue to take a leadership role. My publications on the neurobiology of insomnia have pioneered novel methods of investigation which examine current models of insomnia pathophysiology. My published work in sleep-related eating disorders and nocturnal leg cramps have helped to characterize those common, but little-appreciated sleep disorders. Educating clinicians through visible and highly-cited references and providing novel clinical approaches to treatment have been my goals as a clinician-researcher.